

United States

"THE LICIT IMPORTATION OF OPIUM"



HEARING

BEFORE THE

SUBCOMMITTEE ON CRIME

OF THE

COMMITTEE ON THE JUDICIARY

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

FEBRUARY 27, 1990

Serial No. 89



Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

31-920

WASHINGTON : 1990

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

COMMITTEE ON THE JUDICIARY

JACK BROOKS, *Texas, Chairman*

ROBERT W. KASTENMEIER, *Wisconsin*
DON EDWARDS, *California*
JOHN CONYERS, Jr., *Michigan*
ROMANO L. MAZZOLI, *Kentucky*
WILLIAM J. HUGHES, *New Jersey*
MIKE SYNAR, *Oklahoma*
PATRICIA SCHROEDER, *Colorado*
DAN GLICKMAN, *Kansas*
BARNEY FRANK, *Massachusetts*
GEO. W. CROCKETT, Jr., *Michigan*
CHARLES E. SCHUMER, *New York*
BRUCE A. MORRISON, *Connecticut*
EDWARD F. FEIGHAN, *Ohio*
LAWRENCE J. SMITH, *Florida*
HOWARD L. BERMAN, *California*
RICK BOUCHER, *Virginia*
HARLEY O. STAGGERS, Jr., *West Virginia*
JOHN BRYANT, *Texas*
MEL LEVINE, *California*
GEORGE E. SANGMEISTER, *Illinois*
CRAIG A. WASHINGTON, *Texas*

HAMILTON FISH, Jr., *New York*
CARLOS J. MOORHEAD, *California*
HENRY J. HYDE, *Illinois*
F. JAMES SENSENBRENNER, Jr.,
Wisconsin
BILL MCCOLLUM, *Florida*
GEORGE W. GEKAS, *Pennsylvania*
MICHAEL DEWINE, *Ohio*
WILLIAM E. DANNEMEYER, *California*
HOWARD COBLE, *North Carolina*
D. FRENCH SLAUGHTER, Jr., *Virginia*
LAMAR S. SMITH, *Texas*
CHUCK DOUGLAS, *New Hampshire*
CRAIG T. JAMES, *Florida*
TOM CAMPBELL, *California*

WILLIAM M. JONES, *General Counsel*

ROBERT H. BRINK, *Deputy General Counsel*

ALAN F. COFFEY, Jr., *Minority Chief Counsel*

SUBCOMMITTEE ON CRIME

WILLIAM J. HUGHES, *New Jersey, Chairman*

ROMANO L. MAZZOLI, *Kentucky*
EDWARD F. FEIGHAN, *Ohio*
LAWRENCE J. SMITH, *Florida*
RICK BOUCHER, *Virginia*
JOHN CONYERS, Jr., *Michigan*

BILL MCCOLLUM, *Florida*
GEORGE W. GEKAS, *Pennsylvania*
MICHAEL DEWINE, *Ohio*

HAYDEN GREGORY, *Chief Counsel*

ANDREW FOIS, *Assistant Counsel*

LINDA C. HALL, *Editor*

PAUL McNULTY, *Minority Counsel*

90-602421

KF27
J858
1990d

CONTENTS

HEARING DATE

February 27, 1990.....	Page 1
------------------------	-----------

OPENING STATEMENT

Hughes, Hon. William J., a Representative in Congress from the State of New Jersey, and chairman, Subcommittee on Crime	1
---	---

WITNESSES

Angarola, Robert T., Esq., Hyman, Phelps & McNamara.....	64
Christodoulou, Aris P., Ph.D., president, Penick Corp., Newark, NJ, accompanied by Joseph M. Baorto, vice president, commercial operations.....	65
Haislip, Gene R., Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.....	12
Levitsky, Melvyn, Assistant Secretary of State, Bureau of International Narcotics Matters, U.S. Department of State.....	3
Nystrom, Lloyd W., business director, Medicinal Narcotics, Mallinckrodt, Inc., Specialty Chemicals Co., St. Louis, MO	73
Stratmeyer, Raymond J., vice president, Johnson & Johnson International, New Brunswick, NJ	44

LETTERS, STATEMENTS, ETC., SUBMITTED FOR THE HEARING

Christodoulou, Aris P., Ph.D., president, Penick Corp., Newark, NJ: Prepared statement	67
Haislip, Gene R., Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice: Prepared statement	16
Levitsky, Melvyn, Assistant Secretary of State, Bureau of International Narcotics Matters, U.S. Department of State: Prepared statement.....	6
Nystrom, Lloyd W., business director, Medicinal Narcotics, Mallinckrodt, Inc., Specialty Chemicals Co., St. Louis, MO: Prepared statement	75
Stratmeyer, Raymond J., vice president, Johnson & Johnson International, New Brunswick, NJ: Prepared statement	46

APPENDIXES

Appendix 1.—Public Law No. 100-690, November 18, 1988, Section 4307: United States Reliance on Licit Opium Gum From Foreign Sources.....	113
Appendix 2.—DEA issuance of import permit, 21 CFR 1312.13.....	114
Appendix 3.—A report submitted by Raymond J. Stratmeyer, entitled, "Economic Analysis of the U.S. Narcotic Raw Material Policy," March 1989, by Janusz A. Ordovery and Carl Shapiro	116

8ap71

IV

	Page
Appendix 4.—Attachments to the statement of Lloyd W. Nystrom, business director, Medicinal Narcotics, Mallinckrodt, Inc., Specialty Chemicals Co., St. Louis, MO	137
Appendix 5.—Report to Congress: Licit Opium Review, prepared by the Department of State, Bureau of International Narcotics Matters, and the Department of Justice, Drug Enforcement Administration	210
Appendix 6.—Executive summary and prepared statement of Julian Ormond Green, Chairman of the Poppy Advisory and Control Board, State Government of Tasmania, Australia	263
Appendix 7.—Testimony of Glaxo Australia Pty., Ltd.	302
Appendix 8.—Testimony submitted by Nuzhet Kandemir, Ambassador, Turkish Embassy, Washington, DC	306

THE LICIT IMPORTATION OF OPIUM

TUESDAY, FEBRUARY 27, 1990

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2237, Rayburn House Office Building, Hon. William J. Hughes (chairman of the subcommittee) presiding.

Present: Representatives William J. Hughes, Lawrence J. Smith, Bill McCollum, and George W. Gekas.

Also present: Hayden W. Gregory, chief counsel; Andrew Fois, assistant counsel; Phyllis Henderson, secretary; Paul J. McNulty, minority counsel; and Christine Sesok, intern.

OPENING STATEMENT OF CHAIRMAN HUGHES

Mr. HUGHES. The Subcommittee on Crime will come to order.

Good morning. Today, we will be examining U.S. policy regarding the legal importation of narcotic raw material derived from the opium poppy and how that policy impacts upon the diversion of narcotic drugs into the illicit market.

The opium poppy has been grown in some parts of the world for thousands of years. In the right hands, it can be the source of relief of much human pain and suffering. From this brightly colored plant, raw materials are extracted which are essential in the manufacture of pharmaceutical products widely used as pain relievers and cough suppressants. The final days of many terminally ill patients are made less painful by the use of these drugs. For these reasons, two poppy derivatives, opium and morphine, are included in the U.S. strategic raw materials stockpile.

The poppy also has other uses, such as in cooking. The bagels that many of us had for breakfast this morning, for example, may have been coated with poppy seeds. I just looked at them. I went to three breakfasts this morning, and all I saw was poppy bagels at a distance.

Ironically, this same plant is also responsible for the misery and anguish of millions of people. Morphine can be converted into heroin, a dangerous and highly addictive drug, that is used intravenously by approximately 750,000 people in this country. Experts had once thought that heroin use in this country had declined and stabilized. It was easy to overlook the danger of heroin as cocaine and crack consumed the bulk of our attention.

The truth is, however, that heroin remains a major drug control problem. Recently, we have begun to see an upswing in heroin

abuse in the United States as supplies and purity of the drug have increased while prices have remained stable or even decreased. The number of heroin-related hospital emergency room visits has increased 20 percent in the last 4 years. "Speedballing," a practice in which crack is used together with heroin to lengthen the crack high and reduce the depression that follows it, has been described by one drug abuse expert as "the worst news to the drug abuse control community since the emergence of crack."

History teaches that epidemics of stimulant use have usually been followed by periods of increased use of depressants. Drug Czar William Bennett predicted in his most recent National Drug Control Strategy Report that, if this pattern holds, heroin may well become this Nation's next drug of choice. The problem is by no means limited to this country; many countries all over the world are experiencing large and growing problems with heroin addiction.

The opportunities and dangers presented by the opium poppy are such that the entire world has an interest in ensuring adequate supplies while simultaneously preventing illegal cultivation of the plant as well as diversion of the raw materials from licit to illicit markets. Thus, the licit importation and processing of narcotic raw material derived from the opium poppy is understandably a highly controlled industry, both nationally and internationally.

A major component of U.S. policy is a DEA-promulgated regulation known as the 80-20 rule. This 1981 regulation requires that at least 80 percent of the narcotic raw materials imported into this country come from India and/or Turkey and that the remaining 20 percent come from those two countries or from any of another five specified countries. Of these five, Australia now produces most of the raw material that is not imported from India or Turkey.

In recent years, the continued efficacy of this policy has been called into question as technological advances and market forces have their impact upon the industry. Most importantly, the evidence suggests a vast disparity in the relative success that producer countries have had in preventing illegal diversion and limiting unneeded and dangerous stockpiles. In addition, there is evidence that the potential that the policy represents for manipulation of the market may have, in fact, been realized.

An amendment to the Anti-Drug Abuse Act of 1988 required the administration to undertake a study of this country's policy regarding the importation of narcotic raw material. This report was submitted to the Congress on January 26 of this year. While not unconditionally embracing the 80-20 rule, the report recommends continuation of the rule for a 3-year period, after which a further review would be conducted and the rule reevaluated in light of future developments. In view of the report's own lack of enthusiasm for the rule, it is reasonable to ask what purpose would be served by maintaining the status quo for another 3 years and then conducting yet another evaluation.

This morning, we will be hearing from representatives of the two agencies that had primary responsibility for the production of the report: The Department of State and the Drug Enforcement Administration. We will also be hearing from the three manufacturing companies that are licensed to import these narcotic raw mate-

rials into the country. We have also received written submissions, which will be made a part of the record, without objection.

Before introducing our first witnesses, however, I would like to recognize the ranking Republican, the distinguished gentleman from Florida, for any comments he might want to make.

Mr. McCOLLUM. Thank you very much, Mr. Chairman.

I certainly think this is going to be an interesting hearing today. We have been looking forward to hearing with regard to the review that has been undertaken on the issue of the licit opium, and I am quite concerned about whether or not there are records or indications that we have much of this that is going into the black market and to what degree we will want to examine and reexamine the whole question of the 80-20 rule.

At any rate, without making a formal statement as the chairman has made, because I echo his sentiments, I just want to say welcome to our guests today, and we look forward to hearing from you.

Mr. HUGHES. Our first panel this morning will consist of Assistant Secretary of State for International Narcotics Matters, Melvyn Levitsky, and Deputy Assistant Administrator of the Drug Enforcement Administration, Office of Diversion Control, Gene R. Haislip.

Secretary Levitsky has had a long and very distinguished career with the State Department. He joined the Foreign Service in 1963 and has served abroad in Germany, Brazil, and the Soviet Union. In addition, from 1984 through 1987, Secretary Levitsky served as U.S. Ambassador to Bulgaria.

He has also held a number of positions in the State Department here in Washington, DC, including Deputy Assistant Secretary for Human Rights and Humanitarian Affairs. He has served as Assistant Secretary of State for International Narcotics Matters since June 1989.

Gene Haislip has had an equally lengthy and distinguished career with the Drug Enforcement Administration and is no stranger to this subcommittee. He has been Deputy Assistant Administrator in Charge of the Office of Diversion Control since 1980. In that capacity, he is responsible for the regulation of commerce in controlled drugs and the prevention of diversion into the illicit market. Prior to his present position, he served in DEA as Executive Assistant to the Administrator, Director of Planning and Evaluation, and Chief of Congressional Affairs.

It is a pleasure to have both of you with us this morning.

We have your very comprehensive statements which, without objection, will be made a part of the record, and we hope that you can summarize for us.

Mr. Secretary, welcome.

**STATEMENT OF MELVYN LEVITSKY, ASSISTANT SECRETARY OF
STATE, BUREAU OF INTERNATIONAL NARCOTICS MATTERS, U.S.
DEPARTMENT OF STATE**

Mr. LEVITSKY. Thank you, Mr. Chairman, Mr. McCollum.

I will summarize very briefly to say that we welcome the opportunity to review with the subcommittee the licit opium review that we have submitted. This was a review conducted jointly by INM, my Bureau in the State Department, DEA, and the Food and Drug

Administration. We worked very hard on this. This was one of the first things that I confronted when I came into office, and I had to study it quite a bit to get to understand it, which is one of the reasons why it is somewhat late, which I apologize for, but we wanted to make it right.

If I could just put a little context into what we are discussing for just a few minutes. We look at the situation of opium growth and heroin trafficking around the world as a very discouraging situation. It is discouraging because the illicit production of opium, last year in particular and for the past several years, has been exploding, particularly in places which are denied areas to the United States in terms of its influence—Burma, some areas of Pakistan, and Afghanistan—and we are confronting a situation where there is a very much larger flow of illicit opium and heroin moving through world markets.

Our own situation in the United States still has to be assessed. There are indications that our problem with heroin abuse in this country is getting worse. But I think it is important to understand that, in fact, the problem in other countries is getting far worse.

If you look at the number of addict populations that we can try to determine, or that country's report, that is an exploding figure as well, so that the additional production often is going to other places to feed growing addict populations. So it is a matter of great concern.

You mentioned smokable heroin. That is something that is bothering a lot of people who are looking at the situation. Comments by a number of experts indicate that, in fact, we had better be careful about a heroin epidemic following a cocaine stimulant epidemic.

So these are things that we are looking at, and I just wanted to say that to put what we have here before us today in a little bit of context.

Now to go to this particular question of licit opium. The act directed that this review that we have done determine current and reserve international needs for opium-derived products and the capabilities for meeting these needs, whether the United States should rely on a single country for licit opium gum, whether the United States should encourage all licit opium producers to use the concentrated poppy straw method, and what options would be available to reduce U.S. reliance on opium gum from foreign sources, and when we addressed these questions, the review focused on the 80-20 rule and its retention, the world oversupply of licit opium, India's stockpile, and reports of diversion from licit cultivation, excess production capability in Turkey, and access by U.S. manufacturers to fairly priced and reliable supplies of licit opium.

The 80-20 rule reserves 80 percent of the U.S. market for licit opium to the traditional suppliers, Turkey and India, and makes available, as you pointed out, 20 percent of the market to nontraditional producers which assisted the United States during the opium shortage in the midseventies.

World production and demand, according to our estimates, are roughly in balance for licit opium, but excess stocks remain high, inviting diversion, and this is a matter of concern, but there is no agreement as yet on how to bring down the stocks, and this is something that we need to worry about.

I would mention, Mr. Chairman, that I am planning my first trip to the area to meet with Indian officials, Pakistani officials, and Thai officials on a variety of problems, and I am also planning to go to Turkey. In both India and Turkey I plan to take up the negotiations that are recommended in the licit opium study and deal directly with the officials there. I have already had a chance to meet in a preliminary way with them at some of the U.N. meetings we have had recently, but I think a visit to the two countries in particular will help us carry out the purposes and recommendations of this report, and I will do that at the end of March and in early April.

I would say that in terms of this issue, and particularly from the standpoint of those of us in the Department involved in narcotics control, control of opium production and diversion are the driving force behind U.S. licit opium policy, but of course the needs of our own pharmaceutical industry are also of major concern.

Finally, let me just summarize the major findings of the review in a brief way. First, we believe that present and future U.S. licit opium needs can be met under the 80-20 rule. Second, the U.S. Government opposes poppy growth or cultivation within our own borders, and we believe we need to continue to rely on foreign sources; the United States has no need of a source other than India for opium gum. Third, the 80-20 rule should be maintained for an additional 3 years while we work with India and Turkey to decrease stockpiles and further improve controls and production.

That is the end of my summary statement, Mr. Chairman. Thank you very much.

Mr. HUGHES. Thank you, Mr. Secretary.

[The prepared statement of Mr. Levitsky follows:]

TESTIMONY
ASSISTANT SECRETARY MELVYN LEVITSKY
BUREAU OF INTERNATIONAL NARCOTICS MATTERS
DEPARTMENT OF STATE
to
SUBCOMMITTEE ON CRIME

HOUSE COMMITTEE ON THE JUDICIARY

February 27, 1990

MR. CHAIRMAN:

The Department welcomes this opportunity to examine with the Subcommittee the Licit Opium Review mandated by the Anti-Drug Abuse Act of 1988 (Section 4307, P.L. 100-6900) and conducted jointly by the Department of State (INM), the Department of Justice (DEA) and the Department of Health and Human Services (FDA). The Review was submitted to Congress on January 26, 1990.

In developing this report, representatives of the reviewing organizations made on-site visits to the principal suppliers of opium derivatives for the United States pharmaceutical industry: India, Turkey and Australia. In addition, the three American importers and processors were extensively interviewed and were invited to provide written statements in response to specific questions submitted by the review team.

The Anti-Drug Abuse Act of 1988 directed that the Review determine:

1. The current and reserve international needs for opium-derived pharmaceutical and chemical products, and the relative capabilities for meeting those needs through the opium gum process and the concentrated poppy straw method of production.
2. Whether the United States should continue to rely on a single foreign country for all its licit opium gum.
3. Whether it should be United States policy to encourage all countries which produce licit opium to use the concentrated poppy straw method of production.

- 2 -

4. What options are available, consistent with treaties to which the United States is a party, to reduce United States reliance on licit opium gum from foreign sources.

In addressing these questions, the Review focused on several main issues of concern. Among these were the "80-20 Rule" and whether it should be retained; the world oversupply of licit opium; the Indian stockpile and diversion from licit production; excess production capacity for concentrated poppy straw in Turkey; and the need for U.S. manufacturers to have access to reasonably priced and reliable sources of opium.

The "80-20 Rule", in effect since 1981, stipulates that 80% of the U.S. market for licit narcotic raw material be reserved for the "traditional" suppliers: India and Turkey. The remaining 20% of the market is open to Australia, France, Hungary, Poland, and Yugoslavia. This policy was intended to promote the traditional U.S. interest of limiting the number of licit opium producing nations. It recognized the unique role of the traditional suppliers while at the same time acknowledging those non-traditional producing countries which assisted the U.S. during the opium shortage of the mid-1970s.

Licit opium and several of its derivative alkaloids such as morphine, codeine, and noscapine are used in modern medicine. Preparations based on opiates produce analgesic, anti-tussive, sedative, and antidiarrheal effects.

World production and demand for licit opiates have been in approximate balance in recent years. Excess stocks, however, remain high. This situation invites diversion. Although there is almost unanimous international agreement that stock levels must be brought down, there is no agreement as to how this should be done.

India has not been able to significantly reduce its stockpile of opium gum which now totals about 2,000 metric tons, although it has markedly decreased the areas licensed for poppy cultivation in the last ten years. Maintenance of a traditional peasant agriculture, dependent on poppy for oil and edible poppy seed as well as cash income, is a political issue in producing constituencies, making further reductions difficult. India's competitive position has waned with the decreasing need for the noscapine alkaloid which (so far) can be obtained only from Indian opium gum. The large stockpile is a matter of concern because some intelligence reports indicate that raw opium may be diverted from licit production at the farmgate. The diverted opium does not seem to be in major

- 3 -

quantity and seems to be primarily destined for India's domestic users.

Turkish production is limited to concentrate of poppy straw (CPS) which is processed in its alkaloid plant. Turkey is in the process of expanding its licensed areas for opium poppy cultivation and is reported to be planning the opening of a second production line in its plant in order to take full advantage of its capital investment. These actions are being taken despite current market conditions which show neither a need for the increased production nor a world-wide ability to readily absorb it. However, Turkey has no diversion problems to date.

Although control of opium production has been the driving force behind the traditional U.S. licit opium policy, the needs of our pharmaceutical industry must also be considered. During the 1980s, American processors have been able to fulfill their needs from the several supply countries, subject only to the limitations of the "80-20 Rule." They have had access to plentiful, reliable supplies and, due to the highly competitive nature of the market, they have been able to purchase opium at very fair prices.

Each company expressed the desire to have continued access to opium gum, one more strongly than the others. This need for opium gum reflects their particular needs for alkaloids other than morphine and codeine. Indian opium gum appears to be preferred for its noscapine and thebaine content while concentrate of poppy straw is favored when morphine and/or codeine are the primary considerations.

The major findings and recommendations of the Review include:

1. LICIT OPIUM SUPPLIES SUFFICIENT. Current procedures, based on the "80-20 Rule" have provided the United States with several reliable sources for licit opium for its pharmaceutical industry. We are confident that future needs can also be adequately met under these procedures.
2. RELY ON A SINGLE COUNTRY FOR LICIT OPIUM GUM. Since the United States government has consistently opposed the growth of opium poppies within its borders, and will continue to do so, we will continue to rely on foreign sources for needed licit opiate material.

- 4 -

Opium gum and CPS are not fully interchangeable; the latter generally lacks the alkaloid noscapine. Noscapine has no current medical use in the U.S., but it has some value as a minor U.S. export, mainly to Japan.

Currently, the U.S. has no need of a source, other than India, for licit opium gum. Present market trends indicate that if India does not convert at least a part of its production to the CPS process, it may lose a major part of its U.S. sales.

Turkish CPS sells for about 60% less per medically useable unit than Indian opium gum, and the production process is less costly and labor intensive. Given the option, U.S. processors are increasingly turning to the use of CPS. This may result in India's loss of a substantial part of its U.S. market to Turkey unless India converts at least partially to CPS.

Conversion to CPS would make it easier for India to control diversion of opium from the fields. The Indians, however, have not been able to allocate the large amount of funds required to convert to this advanced technology.

3. EXTEND THE "80-20 RULE." The "80-20 Rule" should be maintained in its present form for an additional three years. During this period the United States should continue to support India and Turkey as traditional suppliers of licit raw materials subject to the conditions of the Rule. The Rule should be reexamined at that time to determine its continued status or modification. The Rule may, however, be modified or abrogated prior to that date if formal or informal agreements by suppliers should establish price levels above customary competitive levels.

4. INDIA: NEGOTIATIONS & ASSISTANCE. The U.S. Government is concerned about the levels of drug trafficking and the potential for opium diversion and illicit production in India. Trafficking organizations are becoming entrenched and some heroin refining has already occurred. The Indian Government is aware of our concerns and has taken steps to implement legislation and strengthen their investigations. The Indian Government has cooperated closely with us in efforts to stem trafficking and in joint investigations.

The United States should enter discussions with India to encourage action to reduce opportunities for diversion from the field by expansion of enforcement and inspection

- 5 -

control. We should also seek ways to assist India in reducing its opium stockpile by bringing its production into line with realistic market conditions.

The United States should continue to support India's status as a traditional supplier of licit narcotics material subject to the conditions expressed in the "80-20 Rule."

India should be encouraged to consider a partial conversion to the concentrate of poppy straw process in order to reduce diversion, simplify enforcement and regulation, and to remain competitive in the world market which increasingly prefers using concentrate of poppy straw. Conversion to CPS would also provide India with the means to meet its own requirements for narcotic alkaloids.

The United States should provide direct and indirect assistance, to the extent available, to aid India in meeting these objectives.

5. TURKEY: SUSTAIN AND ENCOURAGE ALTERNATIVES: Turkey has established control over its poppy crop and eliminated diversion into illicit channels through tough enforcement and insistence on the CPS method. However, expansion of poppy cultivation into new areas could potentially dilute the effectiveness of current controls. This expansion of cultivation is being undertaken to enable Turkey's alkaloid plant, long operated at less than full capacity, to expand production to fully efficient levels. It is understandable that the Turkish government wants to get full use of its significant capital investment in the CPS factory, but it is doubtful the world market can safely absorb the total production capacity of this plant in the near future. The production facilities, however, could be used to process other (non-narcotic) products.

The United States should continue to support Turkey's status as a traditional supplier of licit narcotics material subject to the conditions expressed in "80-20 Rule."

The United States should encourage Turkey to produce alternative, non-narcotic products as a means of utilizing the full capacity of its CPS factory rather than expand poppy cultivation and production of CPS. Alternatives range from bella donna to licorice.

- 6 -

Mr. Chairman, in closing I would like to state for the record that the Department of State has looked very closely at the licit opium issue and devoted much time and attention to our review. We consider the licit opium issue a very serious narcotics control matter which merits high-level attention from our government and the international community to make clear the difference between legitimate trade for medical purposes and illicit narcotics trafficking that is without regard for collective human welfare. We intend to continue our close cooperation with the Governments of Turkey and India in an effort to satisfy international pharmaceutical needs and to prevent diversion. We look forward to working closely with those governments to make greater gains against opium and heroin trafficking in the years ahead.

Thank you for this opportunity, Mr. Chairman.

Mr. HUGHES. Gene, welcome.

STATEMENT OF GENE R. HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF STATE

Mr. HAISLIP. Thank you, sir.

I have submitted a statement for the record, and I would like to summarize several of the features in it which I hope will provide you some additional insight into our policy and the reasons therefore.

As you have stated, the Drug Enforcement Administration is responsible not only for the suppression of the illicit traffic in controlled substances and narcotics but also for the control of legitimate sources, both domestic and foreign, that affect the United States in order to prevent their diversion into the illicit traffic, which, in spite of our best efforts, of course, continues to be a large national problem in and of itself.

We are concerned in this testimony, of course, with the opium and the narcotic products that are derived from it which, in many ways, represents the first controlled substance that we had to deal with in our national policy from the standpoint of addiction and abuse.

As you have pointed out, opium and its derivatives is and has been both a blessing and a curse. It is a blessing because it provides the source of very important medications which we use a great deal in our country, as is the case around the world, for the relief of pain and treatment of other diseases. It is a curse because it is also quite often the source of a very severe and debilitating illicit drug traffic, and it happens that in this context the United States is probably affected the most by both of these particular activities. That is to say, we probably purchase between 40 and 50 percent of all of the narcotic raw materials that are legitimately sold in international commerce. By the same token, it is well known that we are also perhaps the major target for the illicit heroin traffic.

So we certainly mirror both of these aspects of what we are talking about and have major interest in both of them, and I think it is because of that, in large part, that the United States has provided so much of the traditional leadership in international control, beginning with the Shanghai Convention in 1909, which is a correction of the date that occurs in my written statement, if I may, for the record, and we have always viewed the control aspect over this commerce to be the most important aspect, not from the standpoint of destroying legitimate commerce but from the standpoint of the perception that this kind of legitimate commerce cannot be left to the free market and to competition but does require stringent international and national controls to ensure that it is not a source of illicit drug traffic. That has been the policy of the United States ever since we have recognized the nature of this commodity that we are talking about, and it continues to be our policy, not only internationally but domestically as well.

As you know, our controlled substances law does not permit the importation of finished drug products, controlled drug products, from any source in the world unless there is a national emergency.

That is because of the stringent controls which our law applies to our industry and therefore provides this measure of protection from foreign sources where there may not be adequate controls, and our opium policy is the same.

For that reason, for most of this century the only narcotic raw material which we have permitted to be imported into the United States was opium, and I think it is important to point out that, whereas the United States is the largest importer of narcotic raw materials in the international market, we have voluntarily foregone our treaty right to produce our own supply domestically in favor of our international policy of control, which has been to support those traditional sources of legitimate opium and narcotic raw materials.

Our policy was predicated upon the recognition that the cultivation of opium has been practiced for hundreds, even thousands, of years in certain parts of the world, and it is engaged in by many hundreds of thousands of peasants. It would be extremely difficult for various sociological reasons to eradicate that production in any reasonable time scale, and therefore we have elected to support those traditional sources for legitimate commerce, foregoing our own treaty right, as a control mechanism provided that, number one, the source was adequate for our national legitimate needs and, number two, those governments where this traditional production existed undertook necessary measures to control that production and safeguard it against diversion into the illicit drug traffic.

That has been the nature of our policy throughout this century, and that is the reason why only opium was permitted to be imported in the United States, and that is the only reason why the United States does not cultivate its own supply, as it is entitled to do so under international agreements.

Well, the problem, I think, developed in the sixties, when we did see a growth in the heroin abuse problem in the United States to new epidemic proportions, and we discovered that probably 80 percent of that illicit heroin was coming from one of those traditional sources that we imported from, Turkey. As a consequence of that, we made some very strong representations through our State Department to the Turkish Government to ban the production of opium, which finally they agreed to do, and in 1972 the Turkish Government did ban the production of opium, and there were several consequences of that.

One of the consequences was that the heroin traffic coming from Turkey virtually disappeared, and there is very little of it that actually comes from Turkey today. So I think that that was a very successful objective that we achieved.

Another consequence of it was that Turkey lost its market share for supplying the United States with material, and it had supplied approximately one-third of all of our national needs prior to that time. But when they no longer harvested opium, they lost that market share. That was a sacrifice that they made, that and any other market shares they had with any other country in the world.

The third thing is that it appears that it was in some way related to what then became a shortage of opium for legitimate purposes and needs for our country. Well, for whatever the reason, there was a shortage of opium that occurred, or allegedly occurred, and

which we believed did occur in the midseventies, and that required us to consider for the first time departing from our normal practice of importing only opium as a raw material.

There was another material available in the world called CPS, or concentrated poppy straw. It is a more refined product. We would not normally have permitted that to be imported under our laws as a refined product, but we had the power to do so on an emergency basis under the law, and so, using the emergency provisions in 1974 and 1975, we did allow, for the first time, the importation of this much more refined product from several countries—France, the Netherlands, Yugoslavia, and later Australia as well. That is how we came to the importation of concentrated poppy straw from other than traditional sources, such as Australia, France, and others.

In 1980, we realized that there was no longer a shortage, there was no longer an emergency situation, it was now necessary to address this policy, and that gave rise to the so-called 80-20 rule. At that time, we decided that our traditional policy was the correct policy, we should support those traditional sources—Turkey, which had made sacrifice, and India, which was a source of necessary opium for our industry—but we also recognized that certain countries had certain equities we should recognize because they had supplied us during periods of shortage, and that led to the list of nontraditional suppliers from whom we would permit a modest amount of importation, up to a level of 20 percent of our national needs. This provided us a hedge against various climatic, political contingencies that might occur in the traditional sources, and that is why we have the 80-20 rule. It is nothing more than a modification of the traditional rule that we have had throughout this entire century to recognize the equities of some of those countries that helped us in a time of shortage.

Together with the State Department, which has a major interest in this because of its impact on international control, we undertook this current review, as it has been recited to you. I would just like to note a couple of things that have come out of that review. The first thing we might point out is that there has been no shortage of supply for U.S. legitimate needs, none whatsoever. The second thing we might note is that this commodity, unlike virtually every other commodity in the world, has actually gone down in price. Our companies, I am glad to say, are paying less for this commodity than they were paying in 1980; the price has declined, which is, I think, a tribute to the fact that it has worked in that respect as well.

The situation in Turkey continues to be a favorable one, in the sense that the Turkish Government seems to vigorously suppress the heroin traffic, and it is not a major source of heroin for the United States, as it once was.

India is a much more difficult situation, but I have been there twice myself, and I can say this: Although the situation is complex and difficult, the Indians have enacted new legislation which is much more powerful than they had in the past, and they have established some investigative capacity which, if inadequate to the needs, is nevertheless superior to what they had several years ago.

The other thing about our policy is that it has discouraged the growth of other international sources, and there have been no major entrants into this market of supplying this raw material, so that our rule has worked to keep the level of supply and demand somewhat in balance. I think that this is what led us jointly to the conclusion that Secretary Levitsky has stated in his summary.

By the same token, I think it is only rational that we monitor a policy of this kind very closely. We obviously have concerns, which have been expressed in our report, with regard to the situation in India and other places in the world, and it is appropriate that we should study this and negotiate, as appropriate, to ensure that the conditions continue to be met—that is to say that efforts are made to control these sources of traditional production and that the sources for legitimate material are adequate for the United States.

If we do find in some future date that our traditional policy of sacrificing our own right to produce this material in favor of supporting others out of consideration of control, if that policy is no longer valid, then the prohibition on our own citizens is no longer valid and we must consider our own domestic sources at least in addition to those of other industrialized countries who wish to supply us but who have no such control problems that we need to respond to.

I hope this summary has helped enlighten you a little bit as to the nature of our policy and how it was derived, both the present study and historically.

Thank you for your attention.

Mr. HUGHES. Thank you very much, Mr. Haislip.

[The prepared statement of Mr. Haislip follows:]

**PREPARED STATEMENT OF GENE R. HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR,
OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S.
DEPARTMENT OF STATE**

Chairman Hughes and Members of the Subcommittee on Crime: I am pleased to appear before you today to discuss the licit importation of opium into the United States.

The opium poppy, *Papaver somniferum*, has been cultivated for medicinal purposes for centuries. It is the source of opium and contains as many as 20 different alkaloids, including morphine, codeine, and thebaine. Many drugs have been synthesized from the opium alkaloids which are important therapeutic agents having potent analgesic, antitussive and antidiarrheal effects. When used judiciously by competent medical practitioners, these products provide therapeutic relief to millions of patients. However, when used improperly, these same products can lead to widespread addiction and have caused incalculable pain, suffering and death.

The United States is the world's largest single purchaser and consumer of licit opium raw materials, averaging about 60 tons of anhydrous morphine alkaloid (AMA) annually, or about 43% of the world market for such material. Opium raw material (a.k.a. Narcotic Raw Materials or NRM) are obtained in several forms. Crude opium gum is obtained by lancing the unripe capsules of the opium poppy and collecting the milky exudate. Opium gum is approximately 10% anhydrous morphine in content. Concentrate of poppy straw (CPS) is produced through a fairly sophisticated industrial process, whereby the ripe unincised poppy plants are processed to produce a crude extract with a content of approximately 80% or more anhydrous morphine.

The challenge to U.S. policy, in conjunction with international authorities, is to limit world production to levels commensurate with legitimate global needs. This policy goal will insure that the world community is able to realize the full benefit of the proper therapeutic use of these products while at the same time reducing the opportunity for diversion and the consequent misuse and abuse of these drugs.

HISTORICAL U.S. POLICY—RELIANCE ON TRADITIONAL SOURCES

The United States has been a leader in dealing with global issues involving opium production, starting with the first international conference on this topic in Shanghai in 1908 and continuing through to the present annual meetings of the Commission on Narcotic Drugs in Vienna. The Narcotic Raw Material policy which we have maintained throughout this period has consistently favored the use of traditional foreign sources of poppy cultivation to satisfy our needs. It must be noted that a very important aspect of this policy has been a self imposed ban on domestic cultivation of the opium poppy. Our policy of reliance on traditional source countries has been pursued on the assumption that it would:

- 1) discourage other nations not now cultivating narcotic raw materials from doing so, or from expanding existing production and thus adding to the possibilities for diversion to the illicit market;
- 2) help insure that production in the "traditional producer" countries, i.e., Turkey and India, went to satisfy the legitimate market and not the illicit market;

- 3) provide the United States with specifically related economic leverage to help encourage and assist those countries in controlling production and combatting diversion;
- 4) provide the United States with an adequate and reliable supply of narcotic raw material.

DEVELOPMENT OF PRESENT POLICY

The years 1972/73 saw dramatic changes in the international opium supply and demand situation. Unfavorable weather conditions in India and Russia reduced poppy straw and opium yields considerably, and Turkey banned opium cultivation. All this happened at a time when U.S. codeine consumption was increasing significantly and when U.S. drug manufacturers were projecting a thebaine need that would not be met by processing the usual quantities of opium necessary to satisfy U.S. morphine/codeine requirements. To satisfy the immediate concerns, the U.S. Government released gum opium from the national strategic stockpile, bought seized opium and looked for alternate narcotic raw material sources. Concentrate of poppy straw was imported under the emergency provisions of the Controlled Substances Import/Export Act from non-traditional source countries. Thus, the traditional U.S. policy of favoring traditional sources had to be temporarily compromised to insure a continuing supply of narcotic raw material.

By the late 70's, an oversupply of narcotic raw material had developed. This was a matter of concern both to the U.S. and to the international community. The United Nations Commission on Narcotic Drugs (CND) adopted resolutions in 1979 and 1980

calling on importing nations to support the "traditional" narcotic raw material producing countries. The intent of these resolutions was originally to help India and Turkey dispose of their narcotic raw material surpluses and to guarantee them substantial foreign markets in the face of increasing competition from non-traditional nations. However, several nations which had expanded production in part to satisfy U.S. needs during the 70's continued to seek and claim special consideration for permanent access to the U.S. market.

It was within this context that the U.S. developed the so-called 80/20 Rule. Based on U.S. needs and circumstances, a closed list of seven supplier countries was compiled. These would be the only nations allowed to export narcotic raw materials to the U.S. In consideration of the fact that the United States had encouraged increased CPS manufacture by France, Poland and Hungary during the "opium shortage" of the mid-seventies, and also recognizing Yugoslavia's minor exports, and Australia's importance in the advent of crop failures in the northern hemisphere, these five non-traditional countries were included. Since Turkey and India were considered to be the traditional supply countries deserving of U.S. support, a policy which gave priority to these two nations was developed, such that they were guaranteed at least 80% of the U.S. market. A significant consideration in adoption of this system is that it established defined alternate sources of supply in case India and Turkey were unable to satisfy our narcotic raw material needs. This Rule became effective September 17, 1981 and remains in effect today.

SITUATION REPORTS —TURKEY AND INDIA

In view of their special status as traditional source countries, it is necessary to include a brief situation report on both Turkey and India in any examination of NRM policy.

Turkey

Turkey has made substantial efforts to assist the world community and specifically the United States by removing itself as a source for heroin. In 1972, Turkey banned opium production completely, thereby losing its share of the world market, and did not resume cultivation until 1974/75. At that time, Turkey converted to the CPS process and opium gum production was prohibited. These actions were taken at the request of the U.S. and were undertaken at some considerable cost to Turkey. These actions must be considered in any review of our narcotic raw material policy.

Another factor to consider is the impact of our assuring a stable market for Turkish CPS. Turkey has made a substantial investment in its poppy straw processing plant at Bolvadin and poppy growing is a traditional peasant industry operating under license from the government. It would be assumed that Turkey would continue cultivation and production even without guaranteed access to the U.S. market. This would create an additional risk of diversion and further exacerbate the already high level of global inventory of NRM.

India

The situation in India is critical. It is the sole provider of gum opium to the licit world market and more than 95% of all the opium produced for licit use comes from India. In response to the urging of the international community and in recognition of the decreasing market for gum opium, India has greatly reduced the area of land under cultivation for opium. Indeed, the amount of opium produced in 1988 was 563 tons, the lowest since 1967 (with the exception of 1984 when production was affected by adverse weather conditions). Despite this reduction, India's stockpile grew last year since exports of opium amounted to only 427 tons, the lowest since 1981. Thus, despite the dramatic decrease in cultivation of the opium poppy, India presently has in stock approximately 2,000 metric tons of gum opium, almost 5 times the amount which it was able to sell in 1988. Inasmuch as the U.S. is India's largest customer, the consequences to India's ability to reduce this inventory without continued guaranteed access to the U. S. market are clear.

India's cultivation of the poppy for gum opium production represents an explosive potential for diversion which is of great concern to both the U.S. and the international community. There have been reports of heroin laboratories operating in the licit growing areas. There are a number of actions which we would like to see the Indians undertake in order to reduce the threat of diversion from the poppy fields. First, we strongly recommend increases both in security measures and in enforcement activity in these areas since these are actions which would have an immediate impact on the diversion problem. Second, as a long-term solution to this problem, we suggest that the Indian government consider shifting from the production of gum opium to the production of concentrate of poppy straw in order to eliminate itself as a source for heroin production. Third, we

encourage India to enact and enforce strong chemical control legislation. Specifically, controls are needed on chemicals which are used in the production of heroin such as acetic anhydride.

In short, we look to the Indian government to continue to take responsible actions to reduce the threat of diversion. we recognize that due to various domestic economic reasons, it is unlikely that further large scale reductions in cultivation will take place in the near future. However, actions such as increasing enforcement activity, switching to CPS production and enforcing strict chemical legislation represent concrete and effective responses to this problem which India can undertake. However, it must be recognized that part of India's motivation in this regard would be the guarantee of continued access to our market.

NRM Policy Objectives

Any evaluation of the Narcotic Raw Material policy should include examination of the following policy objectives:

- 1) **Balance and demand**—one of the principal objectives of the U.S. narcotic raw materials policy should be to deflate the current world overproduction and the competition for U.S. markets which have led to the dangerous oversupply situation that now exists.
- 2) **Guard against diversion**—a principal U.S. policy objective is and has been to insure that nations which produced narcotic raw materials undertook measures designed to eliminate diversion at all points of the process. This should always be a primary focus of any policy decisions which we make.

- 3) **Insure an adequate supply at reasonable prices**—another objective is to insure that the U.S. has a reliable supply of reasonably priced narcotic raw materials which will not be interrupted or seriously jeopardized by either political or climatic events or by shortages resulting from the lack of predictability in the U.S. market.

80/20 Rule Evaluation

The "80/20 Rule" must be evaluated on the basis of the limitations of any and all such policies. It did not, and could not, seek to guarantee that:

- 1) all production within these countries would be purchased;
- 2) all national stockpiles of opium or narcotic materials would disappear; and
- 3) all diversion would be eliminated.

Success of 80/20 Rule

The policy has been successful within the context of its more realistic set of expectations and this success may be summarized as follows:

U.S. narcotics manufacturers have enjoyed a reliable and competitive supply of narcotic materials at low prices. No further world-wide proliferation of narcotic crop cultivation or production has resulted out of anticipation of possible access to U.S. markets. Moreover, the Rule has provided us with a mechanism by which we can have

influence both on the quantity of narcotic raw material produced in source countries and on the actions of these countries to prevent diversion.

CONCLUSION

In summary, we can say that the 80/20 Rule has met its goals. It has discouraged additional opium cultivation through limiting access to the U.S. market to designated countries and it has favored India and Turkey as traditional source countries who have made significant domestic sacrifices in this area. The system has worked to fully satisfy U.S. needs without a negative economic impact on the American consumer while at the same time providing us with the ability to strongly pursue foreign policy goals regarding opium cultivation.

The important policy issues of world oversupply which lead to the various U.N. resolutions upon which the 80/20 Rule is based still exist. There may well come a time when other solutions to this problem become appropriate. However, now is not that time. The United States, a world leader on drug control issues, has made a firm commitment to support traditional sources of NRM. A recent joint DEA/State Department study found no reason to modify that commitment. An important issue which bears mentioning a second time is that the long standing U.S. policy of reliance on traditional foreign sources is the only reason that there is no domestic cultivation of the opium poppy. If it is determined that we should no longer favor our traditional sources of narcotic raw material, there is no reason why we should continue to preclude U.S. farmers from cultivating the opium poppy.

Mr. Chairman, this concludes my statement. I appreciate this opportunity to discuss the licit importation of opium into the United States. I will be pleased to answer any questions that you may have.

Mr. HUGHES. First, I don't understand your suggestion that if, in fact, our policy goals are not being achieved, then the only option is to review our decision not to grow poppy in this country. Why is there such a connection there? I mean, we may or may not decide it is a matter of policy, which has nothing to do with economics, that we do not want to grow poppy in this country and yet allocate a larger share to the so-called nontraditional countries. Why the nexus? Why do you suggest a nexus between the two?

Mr. HAISLIP. Well, the nexus is a historical one. That is the basis of our policy.

Mr. HUGHES. But, as a matter of policy, we could change our policy or not change our policy. We can, in fact, deal with the problems of diversion, amassing inventories, and manipulation of market without growing poppy in this country, can't we?

Mr. HAISLIP. Well, may I cite the example of France. France is a producer of CPS, and they have occasionally sold to the United States, and it is a very industrialized country. I would think it would be illogical to grant rights to French citizens that we deny to our own citizens. Certainly we are as capable as France of controlling such activity.

Mr. HUGHES. We are, but it is a matter of policy. You haven't answered my question. What is the nexus? We could decide as a matter of policy that we still don't want to grow opium in this country, ought not to, in fact, exercise our rights under international treaty arrangements, and still attempt to deal with the so-called manipulation, or possible manipulation, or diversion, or lack of controls in connection with diversion, or the stockpiling in other countries, could we not?

Mr. LEVITSKY. May I just offer the general view on this?

Mr. HUGHES. Of course, Mr. Secretary.

Mr. LEVITSKY. We, of course, have not made any determination of this kind of situation, and I am certain there would be a great deal of reluctance to allow the growth and cultivation of opium in this country, because then it would be yet another place where it was grown.

Mr. HUGHES. I understand that standpoint.

Mr. LEVITSKY. So, you are right, there are a number of ways we could decide on this if we ran into problems with this particular rule.

However, I think the argument might be in this country that if we are departing from the traditional producers and importing more from a developed country, the argument might be then, why not have our own people or companies here produce it here at a cheaper cost and create an industry here?

Now some of us would be very much against that, but I am just saying, that could be an argument that would be advanced by some if this rule were changed to the benefit of the developed countries rather than the traditional suppliers.

Mr. HUGHES. Of course you are going to have that argument, but that is not my point. Mr. Haislip would seem to suggest—and I am just challenging this—that we would not deal with diversion or the amassing of stockpiles and potential manipulation of price without revisiting the whole question of—

Mr. LEVITSKY. No, I don't think that—

Mr. HUGHES. Maybe I misunderstood.

Mr. Haislip. Let me clarify that. First of all, as the secretary has said, we have not addressed that, because we do believe that the correct policy, the policy that we have had for all of this century, is the correct one, so we have not addressed it.

I am pointing out that that policy is historically based, the policy of banning production in the United States, I believe, on the desire to support and control these traditional sources, it is not based on a desire to support sources from industrialized countries.

The only other thing that needs to be pointed out: As you know very well, the products of all of this narcotic raw material—that is, major narcotic drugs such as oxycodone and codeine—are the subject of considerable diversion in the United States, considerable diversion and illicit traffic already. So we have to deal with domestic diversion problems all of the time, and I am just pointing out the obvious, which is, the Governments of France and Australia and other industrialized governments are able to deal with and control those problems with regard to poppy production, and I think Americans can do what they can do.

Mr. HUGHES. I understand, but I also understood what you were saying, Mr. Haislip. You were suggesting—and I have heard it before—that we should not revisit this whole question of the 80-20 rule without facing that question of whether we want to grow poppy in this country, and, frankly, I, for one, would not want to see us grow poppy in this country. We have enough problems in this country. I suspect that that would be the position of most of the policymakers here on the Hill and, I would hope, in the administration.

But we talk in terms of traditional growing areas, and we talk in terms of certain policy goals, and you would agree that policy has to be reviewed from time to time to see whether or not our goals are being achieved.

Mr. LEVITSKY. That is right.

Mr. HUGHES. I find it interesting that here we have a policy that is based upon the effort of trying to, first of all, keep at a limited number the growers of poppy, opium gum production, and the production of concentrated poppy straw; to encourage the controls in growing areas; to prevent diversion; to reduce the amount of stockpiles of opium gum and concentrated poppy straw so that there isn't the temptation to divert or the possibility of diversion; and to permit market forces to operate in such a way that we don't have any imbalances.

Now neither one of you is going to suggest that we have achieved all those policy goals, I wouldn't think. I mean, I read your statements last night, and neither one of you has suggested that we have achieved those goals.

Now what is your response after this study? Your response is, we will have more of the same; we will put it back in place for another 3 years. That is our response to a whole host of things that are happening: Serious suggestions that there is a manipulation of price; stockpiles have increased, particularly in India; we have a major diversion taking place; some of the figures show that up to perhaps 50 percent in growing areas is being diverted into the illicit market, according to some of the studies.

You shake your head. That is what some of the studies have shown. Anywhere between 10 and 50 percent; we are not sure. Now that is hardly a success story.

Mr. LEVITSKY. Well, first on the question of diversion, I have seen the same stories, and I have also looked at the reports, and I think that there is an open question, but I think there has been great exaggeration about the amount, particularly in India, of diversion.

Now I can't say and nobody can say that they have an exact knowledge of what percent of the growth is diverted.

Mr. HUGHES. Mr. Secretary, in the State Department's own International Narcotics Control Strategy Report for August 1989—and I read from it—"The diversion from the licit to the illicit market in India is between 10 and 50 percent."

Mr. LEVITSKY. That is a very broad range.

Mr. HUGHES. Well, let's assume it is 10 percent.

Mr. LEVITSKY. But the other aspect of this is that, as far as we can tell—and I have to say that on all these statements—as far as we can tell, whatever diversion there is in the Indian licit supply is at the farm gate and seems to go to feed a growing Indian addict population, so that is one aspect of it.

In terms of the Indian Government's efforts in this regard, while they certainly aren't perfect, there is an effort to grab a hold of this problem and to do better. They are constrained by some resources; we know that. But in terms of the attitude, which is an important aspect of this, it is to try to grab a hold of this problem.

There seems to be no diversion from the stockpile, as far as we can tell, and this is based on the International Narcotics Control Board's own inspection of the stockpile at the plant. There is no diversion. That is a good system, and there is no diversion from that plant. There is a large stockpile, and it is a matter of concern, and it is something that we need to talk to them about, and that is the recommendation in the study.

But I think we should not exaggerate the problem itself either in India or in Turkey in terms of what the 80-20 rule set out to do, which was to have some controls over the licit opium growth and provide a stable market for us. I think, in general, what this report says is that that has succeeded, it has not failed.

So what we are saying is that there are some problems that still need to be addressed with the Indian Government and the Turkish Government. We have good relations with those governments. My own assessment, to be quite frank, is that we have not had a close enough discussion with them, nor have we looked at these various problems in a tough way, and we need to do that and give it a chance.

But, generally, we believe that the rule has worked properly for the purposes that were set forth for it.

Mr. HUGHES. Mr. Secretary, I don't know what you mean by "exaggerating the figures." I am taking the State Department's figures. You are saying the State Department's figures are incorrect, 10 to 50 percent?

Mr. LEVITSKY. No, no. I am saying that is a very broad range, and what it says in that report—

Mr. HUGHES. Let's assume it is 10 percent; 10 percent is a pretty significant diversion. Let's take the low end of the scale. I mean, it

could be 10, it could be 50, percent. That is a serious diversion as far as I am concerned, and, frankly, I don't know what you mean by the diversion basically is into the home market. I don't know how you separate that from diversion into our country or any other country or how we can, in fact, permit our rules in some way, indirectly, to exacerbate the problems in India, if that is the case.

Well, in any event—Mr. Haislip.

Mr. Haislip. I would like to reply to a couple of points also.

I know the figures on the stockpile in India show that there is considerable fluctuation. They are lower today than the first time I visited there in 1983. Stockpiles are lower by almost 1,000 tons.

So I don't know that it is really accurate to say they have increased unless you pick a particular year that was low.

Mr. HUGHES. What are the stockpiles presently?

Mr. Haislip. I think the stockpile is around 2,000 tons.

Mr. HUGHES. That is an acceptable number?

Mr. Haislip. No, I am not saying that it is. I am not suggesting that, but what I am saying is that these figures have fluctuated and they have been higher, so there has been some effort, I think, to try to bring this under control in India. I don't think it has entirely succeeded, but there has been a good faith effort made.

The other thing that I would like to say is that diversion is a problem wherever you have these drugs, whether that is India or the United States. We have a major diversion problem here in the United States, and we recognize the responsibility to deal with it, but we don't thereby ban the production of these drugs which are so important for medical practice or react in that way, we try to deal with the problem, and India or other governments can only do the same thing.

Now I think what we want to see in a place like India is an aggressive, good faith effort that shows results and shows progress, and I think that is what our concern is.

Mr. HUGHES. Mr. Haislip, you know, you are straying. I realize we have a diversion problem in this country, and we haven't done the best of jobs in trying to deal with our own diversion problem, but we are talking about an 80-20 rule and how that impacts upon other countries as well as ourselves.

It basically is not totally relevant that we have a diversion problem in this country, except that it is relevant that we haven't committed the resources in years past, as you well know, to get serious about our diversion problem. But we are talking about an 80-20 rule which doesn't seem, in my judgment, to be working very well.

Mr. LEVITSKY. We have a disagreement here, I think, then, because we believe it is working quite well. Let me go back a little bit in background.

Mr. HUGHES. The original draft didn't suggest that. The original draft came to an entirely different conclusion.

Mr. LEVITSKY. Which original draft?

Mr. HUGHES. I am talking about the original draft of the report that was just filed recently. The original draft concluded that, in fact, the rule isn't working, the 80-20 rule, and that we should go to no more than 50 percent to the traditional countries and permit the nontraditional countries to pick up 50 percent. Isn't that what the original draft conclusion was out of the State Department?

Mr. LEVITSKY. There are always a lot of drafts around the State Department, Mr. Chairman. The draft that you have before us is the State Department's—the Government's conclusion, so that is what I go on the basis of.

If somebody who drafted something or has an opinion in the Government and has provided his or her draft to you, then that is what we call a nonpaper in diplomatic parlance, it doesn't have any validity, and I want to make something clear for the record. I said before that we took some time, we delayed the study, because I wanted to make sure, in my case at least, and in our case, in the Bureau of International Narcotics Matters, that we have a full picture. There were some disagreements; there always are disagreements in government.

I looked at this issue, and I said basically, after understanding it—and I tried to understand it first—this rule seems to have worked relatively well; it seems to have carried out the objectives; the onus is on those who want to change it to tell us how it would help the problem: Would it help on the diversion problem in India? Would it help with regard to increasing production in Turkey?

I came to the conclusion after looking at this—and I agree with the report as it is before you, the official report, not some nonpaper—that, in fact, it is carrying out generally the objectives, not without problems. We do have some problems and we need to discuss them, but it is in U.S. national interests to maintain this for the time being.

If we find—and the report says, it sets this out very clearly—if we find that it is not working—and I believe it is working—or if there is an attempt at price gouging at any time, then we will immediately react to that. So I think that is a fair description. We do not believe that it is not working, we believe that it is working, which is why we are recommending that we retain it for 3 years.

We recognize, as you said, the need to review policies, it is always a good idea to review policies, and we will do that as we go along. That doesn't mean that we will keep the rule for 3 years and then suddenly do a review after 3 years. We will continually review this policy as developments occur, and if we find out things that we believe are not in national interests, then, of course, we will accelerate the review and try to come to some conclusion.

Mr. HUGHES. I have a number of other questions, but my time has been up for some time.

The gentleman from Florida.

Mr. McCOLLUM. Thank you very much, Mr. Chairman.

Mr. Haislip, there is no domestic heroin production to speak of in the United States, or is there any at all?

Mr. HAISLIP. We have seized one or two laboratories in the past decade.

Mr. McCOLLUM. But essentially, it is nil, other than the one or two, right?

Mr. HAISLIP. That is right; it is negligible.

Mr. McCOLLUM. If we were to allow licit opium production in the United States, wouldn't we run the risk that poppies would be grown and heroin would be produced?

Mr. HAISLIP. Well, if we did such a thing, I don't think we would run any greater risks than we run by producing narcotics. We are

one of the major manufacturers of narcotic drugs in the world, perhaps the major manufacturer. We run that risk daily, but we do manage to control it quite well at the manufacturing level. Generally, the diversion we see occurs at the retail level, at the pharmacy and practitioner levels. So I think our law has worked quite well to control production.

Mr. McCOLLUM. But, Mr. Haislip, my concern goes to the farm gate question again. If you are talking about us producing these narcotics, you are talking about in the plants, in the actual legitimate plants that are out there, and I don't have any doubt that we have the ability to control the legitimate manufacturing of this.

But I am concerned that if we start allowing poppy plants to be grown in the U.S. legally, then you are talking about just with marijuana or any other plant source; you are going to have a problem with what happens to the plants.

Mr. HAISLIP. Well, let me make it clear that we haven't addressed that question. We are talking about a contingency only. But I think the experience in Australia is a very good one. As you know, Australia has a not insignificant heroin abuse problem itself, increasingly so, and yet Australia has applied controls to their poppy production, which I think are very good. I think they have been very effective in controlling and making sure that diversion doesn't occur. I am convinced that that is the case, and I think Americans can do what Australians can do, sir.

Mr. McCOLLUM. Well, I am just skeptical, I guess, and I hope you understand my skepticism, but I want to know; you are the pro in this; you are the law enforcement man.

Let me ask you something, Mr. Levitsky. In your testimony, the actual printed testimony, you say, "Conversion to straw, CPS, would make it easier for India to control diversion of opium from the fields." How is that? Why would producing the straw instead of the gum make it easier to control diversion? I guess I understand the mechanics of the production maybe, and there must be something in there that would yield that statement.

Mr. LEVITSKY. Gene can probably explain better than I.

Mr. McCOLLUM. OK, go ahead, Gene, if you would.

It just happened to be in your statement; that is all.

Mr. LEVITSKY. No. It is a technical question, but it has to do with the way it is harvested. Rather than lancing and harvesting the gum several times, the whole top of the plant is cut off and taken to the factory, but maybe you can explain the technical aspects.

Mr. McCOLLUM. Gene.

Mr. HAISLIP. I would like to comment on it, because I think it is an important consideration, and I sort of feel that it would be a valuable thing for India to explore this and proceed with this, as Turkey did as a result of our representations to the Government of Turkey.

Basically, what this does is, it greatly simplifies the law enforcement effort, because any time opium is found, it is known to be an illicit commodity. Any time the poppy is found and has been scored, it is known that that farmer or someone responsible for that field has been engaged in illicit harvesting and trafficking.

Now at the present time in India, of course, the opium could be legitimate opium or not; the poppies, of course, all the poppies are

scored, so it makes the law enforcement effort much more complicated. This was the problem in Turkey.

What we found is that, when the Turkish Government banned opium harvesting, so that instead of scoring the poppy and collecting the opium, and required the farmers only to cut off the tops of this poppy and bundle it up in bags and sell it to the Government, as a result of the simplification of the law enforcement problem here, the diversion of narcotic materials in Turkey for the production of heroin virtually disappeared.

Mr. McCOLLUM. So what we are talking about—again, I am just trying to get it intellectually because I have never seen this and don't know the terms—when you are talking about the straw, you are talking about cutting off the top of a plant.

Mr. HAISLIP. Just cutting off the top of the plant.

Mr. McCOLLUM. And producing that, and right now in India they do more to it.

Mr. HAISLIP. They make opium.

Mr. McCOLLUM. They make opium out in the fields, so to speak.

Mr. HAISLIP. That is correct.

Mr. McCOLLUM. And then bring that into the plant for further refining.

Mr. HAISLIP. That is correct, exactly.

So it worked very well in Turkey, and I think it would have similar advantages in India if applied correctly.

Mr. McCOLLUM. The last question I want to ask, because my time is about up, has to do with the whole Turkish demand question. In testimony both you gentlemen have given, I get the impression that Turkey, in its straw production, has a major capacity that is not being met. In other words, they have the ability to produce a whole lot more than they currently have a market for.

But there is an indication in the testimony that is going to be given by the various parties who are the purchasers in the United States, that is yet to come, looking at the written testimony, that they believe that there isn't that, that there is a lot more demand out there, that indeed there is a great deal more demand, and I am just curious if you could run that by me, how that works and where you see demand going, one more time.

Mr. HAISLIP. Well, Turkey has a very large production capacity, they have never used it to its full extent, but at the present time I think there is an adequate supply. I am not convinced. I think if they produced at full capacity, there might be an excess supply.

I would like to point out one factor. There is undoubtedly a greater need for these drugs in the world than is being met, but the people in most of these parts of the world that have this need do not have the money to purchase the drugs, nor do they have the medical infrastructure to deliver them.

Mr. McCOLLUM. I guess the implication of the testimony to come is that Turkey could be so successful, and is being so successful, in the world market. If we let India produce straw or we did other things in terms of changing the formula, the 80-20 formula, we are not going to be hurting Turkey. They are going to have plenty of markets for their products. So that is the issue.

Mr. HAISLIP. The need is there, but the money is not.

Mr. McCOLLUM. All right. Thank you very much.

Thank you, Mr. Chairman.

Mr. HUGHES. The gentleman from Florida.

Mr. SMITH of Florida. Thank you, Mr. Chairman.

I am afraid I have to leave to chair the Democratic Caucus, and I apologize, but I did want to not ask but make a statement to you and have you treat this at some point, if you would.

We have gone over this before, Mr. Levitsky, prior to the time that you became secretary. We have discussed this in the hearings over in the Foreign Affairs Committee on the task force which I chair. We have documented, and our staff has documented, that there has been a significant increase in the stockpile in India of the opium gum and that there has been a significant leakage, including confirmation by Interpol that much of this opium gum, which is easily traceable to India by virtue of its characteristics, has been found in other non-Indian countries.

It seems to me that if we are going to do anything about this problem we have to come up with something better than continuing the same thing we have for the next 3 years while we try and think of some way to treat this matter.

We do have a new government in India. Maybe it is about time we confronted them with it and started to do something now, instead of the Gandhi government, which was, frankly, quite resistant to changing. We have got a lot of our allies, like Australia and others, who want a significant change in this policy.

Mr. LEVITSKY. Well, if I could comment, as we said before, it depends at what point you look at the stockpile. In fact, it is down from some years, but it is still, in our view, too high.

What you say about talking to the Indian Government is absolutely true, and I mentioned, I think before you came in, that I will be taking a trip to the area and plan to take this up with them. We have talked a bit about it with some officials at some of the U.N. meetings, but I think it is something where we have a good relationship with the Indian Government and with the Turkish Government, and we should talk with both of them along the lines of the way we set it out in this report. And so I pledge to you that we will do that, and I said, quite frankly, my conclusion was that we had not had a hard enough go at this issue of what we call negotiations or discussions with the Indian and Turkish Governments. It had not been a sustained effort, and I think that is what we need to do, which is why I support the idea of the 3 years, again, pointing out that that doesn't mean that suddenly, 3 years from now, we say we have to produce another study for the Congress. So we will write it down again; we will have this under continual review and deal with it.

Mr. SMITH of Florida. That is what has happened in the last 3 years. We brought this up a number of years ago, and nothing has changed.

Mr. LEVITSKY. I have made a number of pledges to you and the subcommittee, and this is yet another one, but it is not something that we will handle in that way, I can assure you.

Mr. SMITH of Florida. Thank you, Mr. Chairman.

Mr. HUGHES. The gentleman from Pennsylvania, Mr. Gekas.

Mr. GEKAS. Thank you, Mr. Chairman.

There are a couple of things that I want you to try to clear up in my own thinking. Do you consider that in the maintenance of the 80-20 rule and the guarantees that that produced for Turkey, for instance, that that was an incentive for them to ban back in the seventies the production of opium? Or, if that was not the case, what was the incentive for Turkey to do that? They didn't do that out of good will.

Mr. LEVITSKY. First, we provided assistance at the time, which we pointed out, and that helped them build the modern factory that they now have at Bolvadin which produces the concentrated poppy straw.

I think, two, there was the factor of their relationship with the United States. I mean, the percentage was quite high of illicit heroin coming into the United States that originated in Turkey. What was it?

Mr. HAISLIP. Eighty.

Mr. LEVITSKY. Eighty percent. So that was a factor in our relationship, and I think the Turkish Government wanted to maintain a good relationship with us.

It was not just out of the goodness of their hearts either, because we did provide assistance at the time, which at least helped them to construct this factory, which now is modern and efficient and is a legal industry recognized by the governments of the world as something legal, not branding Turkey with being primarily an illicit producer.

Mr. GEKAS. Was that incentive at all involved in an implicit or express threat to reduce the military assistance?

Mr. LEVITSKY. My reading of the history of this is that I don't believe it was brought up in that way, although the threat in terms of the worsening of the relations certainly must have had an effect at the time.

Mr. GEKAS. Then I take it—and this is where I refer back to the chairman's questioning as to whether or not the 80-20 policy is working—it seems to me that the maintenance of the 80-20 policy is separate and apart from the question of diversion even though you feel that 80-20 remaining in place is our best bet for the future. It cannot deal effectively with all the problems of diversion that are exploding in our face.

Mr. LEVITSKY. In a way, however, I think it does give us more influence over the policies of governments, not only in the sense of political influence, but we have programs in both India and Turkey in terms of training, and we would like to, in fact, increase some of those, particularly in India, in monitoring the fields and monitoring the production. We do this around the world, and so we have a relationship with the Government. The 80-20 rule, which ensures a certain percentage of the market for them, gives us this expanded influence and, in a way, shores up their own determination and will to try to control either illicit production or diversion from the licit growth. That is the way I would put it.

Mr. GEKAS. Is it fair to say that our policy, as you see it, should be the maintenance of the 80-20 for at least 3 years, as you have indicated in your report, plus additional qualities of control that we can install for diversion?

Mr. LEVITSKY. Well, let me say, our policy is not necessarily to maintain the rule for 3 years. What we have said is that we believe it wise to continue our efforts with the two governments and then look at it again in 3 years. The policy is to maintain a rule as long as it is in the national interest of the United States from the standpoint of control as well as assured market for the legitimate use of the pharmaceutical companies.

At the same time, as we have said, we believe the rule has generally and quite well served the purposes of the rule, the policy, and our national interest, and, again, I have searched for ways to look at the other side and say, "Well, would this, in fact, help on what the problem areas are—that is, diversion and illicit growth in those two countries?" And I have yet to come to a positive conclusion on that. That is, I believe that, in fact, this rule does serve this purpose.

There is a lot of opium growing all over the world, and particularly, as I pointed out earlier, in Burma, where we have little influence, and little political influence, over the Government. That has been a main problem these days, and, frankly, the problem with respect to India is less, in my view, in terms of diversion and illicit growth as it is in increased trafficking based on increased production levels in India's neighbors. They are having a difficult time, although they are trying, in coping with transit through their country of illicit opium from Burma and from the Golden Crescent—that is, in Afghanistan and Pakistan. That has become an increasingly difficult problem for them, and we have discussed this with them, and where there are some prospects that we can perhaps assist in this area as well.

Mr. GEKAS. In other words, changing the 80-20 rule to 50-50, or abandoning it, could not help in the question of the Burma syndrome here. Isn't that correct?

Mr. LEVITSKY. Yes, sir.

Mr. GEKAS. So that is the conclusion I am drawing here, that no change of the policy in 80-20 is going to help us with the other adjacent problems that we have on diversion or production illicitly, et cetera.

Mr. LEVITSKY. No, I don't believe so.

Mr. GEKAS. OK.

The other question I wanted to pose was this. I seemed to gather from the report that there is a greater movement in producing synthetics in our country and elsewhere to take the place of those kinds of medicinal substances that are based on the production and refining of opium. Can we look to a day when the demand for opium for the drugs that are now substituted by synthetics more and more—that the demand would be significantly reduced?

Mr. HAISLIP. Congressman, it seems to me rather unlikely. This has been talked about for many, many years. We do have some very good, powerful, effective, synthetic narcotics and pain killers. However, the products derived from this source are very good ones. They are frequently favored by many practitioners in medical practice, they are very commonly used, and I think one has to conclude that there is a considerable future for the utilization of this material for legitimate purposes. I don't think synthetic products are likely to take their place in any foreseeable future. There may be

some adjustment and shifting in the relative percentage of the market, but these drugs are popular with physicians for use with their patients for legitimate purposes.

Mr. GEKAS. Yes, but isn't part of that reason that the cost of research, developing, and producing the synthetics outdoes the ready supply and the relative inexpense of the opium product? If that is the only reason, then we are suffering as a world civilization the continued production of opium simply because it is cheaper.

Mr. HAISLIP. Well, cost is certainly a factor, as you point out, and I don't think we could preclude the possibility at some time in the future of that happening, but I really don't think it is anything that we can anticipate to solve any of the problems we are having to deal with today or that we will have to deal with that we can foresee because, as I say, these drugs are effective when used properly.

Mr. GEKAS. But we are talking about——

Mr. HAISLIP. It is a possibility at some point.

Mr. GEKAS. We are talking about the development, or redevelopment, or redesign of a policy, and somewhere, if we come to grips with redesigning a policy, although I cannot refute your insistence on the maintenance of the 80-20 at the moment as part of that policy—I see no reason why we shouldn't be attempting to look into, as a 50-year policy, the elimination of opium. Now you think that is unrealistic, and it may be, but the policy at least should take into consideration a new world of medicines to take the place of the opium-based medicines.

Mr. LEVITSKY. That may be the case, and, as Mr. Haislip says, that is a possibility. If we think of it in broader drug control terms, though, most of the opium, of course, that is harvested and then turned into other products in the world is for illicit purposes, much, much more than what is for legal purposes, and that is a real problem.

It is no comfort to us, for example, when a synthetic drug is designed that can be produced in the United States in replacement for a drug that comes in from the outside, because it doesn't help on the abuse problem. In fact, it may be something that is fancier or gives a better kick or something like that. So we want to not have that happen on the illicit side to replace whatever, whether it is opium or coca growth abroad.

Mr. GEKAS. We throw our hands up and decide, once and for all, we have to live with opium; the best thing we can do is try to——

Mr. LEVITSKY. Well, our general policy, particularly on the illicit, of course, is to try to reduce demand in this country and supply from the outside.

What I was saying earlier, I think, is a significant feature that some people have missed in terms of where the growth is in the use of illicit heroin; it is not in the United States but in other countries. The growth is fantastic when you look at the numbers of addicts that have multiplied in some of the underdeveloped countries.

Mr. GEKAS. Like India itself.

Mr. LEVITSKY. India itself, and in Pakistan and some other countries. Or, if you look at the Andean countries in terms of coca growth and how much the abuse problem is beginning to affect them internally, part of which is the reason why they are more

concerned about this than they were in the past. This is beginning to affect increasingly larger segments of societies around the world.

We, I believe, are beginning to get a handle on the issue, and, in fact, some of the figures show that the margins are at least coming down somewhat, but that does not apply in many countries around the world; the use seems to be going up, unfortunately.

Mr. GEKAS. Mr. Chairman, I yield back the balance of the time that I abused.

Mr. HUGHES. Used or abused?

Mr. GEKAS. Abused.

[Laughter.]

Mr. HUGHES. I thank the gentleman.

Mr. LEVITSKY. Mr. Chairman, may I make a comment here on something that you said earlier that I wanted to mention to you. There seemed to be some question about the 3-year period of time involved in our report, and I want to make it clear that we would hope to have a continuing discussion with you and with the subcommittee on this.

So, after we have an initial look at this, particularly after the trip that I plan to take out there and assess the results of that trip and other trips, perhaps we could come back again in a shorter period of time and just discuss with you, whether it is informally with the staff or in some way. I don't want you to think that we are looking to keep this in place for 3 years and then suddenly have a report and have it prolonged again. But I think we need to discuss it, and we would be glad to do that.

Mr. HUGHES. I appreciate that, and I would welcome that opportunity. I am happy you are going to Turkey. I visited some of the growing areas and processing areas in Turkey many years ago and came away very much impressed by the manner in which they have implemented controls. They do a very good job, as Mr. Haislip has said, in enforcement, and I just regret that India has not moved in the same fashion as has Turkey. The Turks deserve a lot of credit for responding to our initiatives back in the late seventies and putting in place a regime that I think has been rather effective.

I will tell you what troubles me about the report. Aside from the fact that those that were assigned the task of studying it—Mr. Hesse, Mr. Haislip, and Dr. Nightingale—arrived at a different conclusion initially, recommended, in fact, as I indicated—at least the first draft report suggests—a repeal of the 80-20 rule effective January 1, 1990, and the implementation of a 50-percent rule for the traditional growers. For policy reasons, that was not accepted nor made the final draft, I understand that, but I think that we do have a responsibility to let India, in particular, know that we are not happy with what is taking place. There are suggestions of major diversion into the illicit market. They continue to grow poppy and process it into opium gum, which opens up all kinds of enforcement problems.

Second, the developed countries that import this substance do not generally want opium gum, they want the concentrated poppy straw, and they have had a difficult time getting their supply, and they have had to resort to purchases of opium gum, to their detriment. As I understand it, it requires much more to process, it is

much more expensive, it has byproducts that are often difficult to get rid of, and these dislocations and distortions are being created by the 80-20 rule.

When we recommend, as a matter of policy, the continuation of the 80-20 rule for 3 more years, I am not so sure how much leverage we give folks like yourself that are going to sit down with the Indians, to begin with, because it sounds to me like it is going to be business as usual, and, frankly, I don't think business as usual is acceptable.

Contrary to the suggestion that the rule has no relevance to diversion, I think there is a direct relevance. It is not relevant to the diversion from the illicit market, true. That is, the growing of poppy in India and the growing areas, the farm gate problem where we see that kind of diversion. The rule may not be totally relevant in those other countries that can grow, and poppy, as I understand it, can grow in a lot of countries, many of which do grow it. Afghanistan has a major growing problem at this point and a major abuse problem, and so it is with many other countries.

But on the licit side, the 80-20 rule is relevant because, frankly, our policy would seem to be encouraging, in some respects, the stockpiling. We have 2,000 tons at this point. What is that? A 3-year supply of opium gum in India right now. And, contrary to reports, Interpol has suggested that they are finding Indian opium gum in other places around the world. That suggests some diversion.

We also acknowledge there is a diversion problem in the growing areas because of the lack of enforcement. If our response to that is, well, we are going to put the 80-20 rule back in and give you a virtual monopoly for another 3 years, I am not so sure whether we are sending the right signals.

Mr. LEVITSKY. Well, I asked the other question as well, because I don't think—and, again, there are different estimates, and we don't pretend to have an exact handle on the question of diversion—but I asked the other question: If we didn't have an 80-20 rule, what would then become the situation in India in terms of poppy growth, illicit as well as licit, and would we have a more difficult problem in terms of diversion and in terms of illicit manufacture of heroin?

I came to the conclusion, after looking at this very carefully, that, in fact, the 80-20 rule helped us in that regard and that at least at this point—and I continue to hold that belief subject to our discussions with the Indian Government—that changing the rule at this point would not help us, it would hurt us, and it would possibly stimulate more illicit growth and more diversion from the licit growth in India.

Now I want to point out that all the countries that grow opium legally, that have legal growth, we have good relationships with in the sense of political relationships, so we have a certain amount of influence and we can have a discussion with them, and particularly with the Government of India. I don't believe it is business as usual. I don't think it has to be described that way, because with friends you need to talk about things frankly and describe problems, and I will certainly pass that on, and they will know the attitude that you have and that others have and the concern that we

have as a government about this problem, so we need to work on this.

Mr. HUGHES. They know today that there is a concern, because I am sure that they are aware of the concern being expressed here on Capitol Hill. But let me just, if I might, turn it around on you. What other country in the world, industrialized country, has an 80-20 rule?

Mr. LEVITSKY. As far as I know, we are the only one that has such a rule.

Mr. HUGHES. The only one.

What is to stop any other country basically from growing concentrated poppy straw or processing that from the poppy?

Mr. LEVITSKY. You mean in terms of the illegal situation?

Mr. HUGHES. Sure.

Mr. LEVITSKY. I believe there are U.N. rules which designate countries as able to grow traditional levels.

Mr. HUGHES. There are U.N. rules, and there are U.N. rules.

Mr. LEVITSKY. No, no, but I mean in terms of recognized ability to grow opium legally.

Mr. HUGHES. I think the best thing that could happen to India at this point, which, as I understand it, is subsidizing the poppy growing industry, would be for the market to be a little freer. If, in fact, the monopoly that they have lulls them into a false sense of security and they don't make it a priority to effect controls in the growing areas, I think our policies are somewhat misplaced.

Mr. LEVITSKY. Well, I would be somewhat concerned—and, again, you can't predict the effect of something until it actually is put into effect—I would be concerned about the relative difference between the black market price and the legal price, and that is part of the diversion problem now, but I would wonder what would the growers that were growing a crop that had a certain market, and an assured market, what would they do if, in fact, that assured market wasn't there. Would they go into illicit growth? And then, what would be the attitude of the Indian Government? My assumption is, the attitude of the Indian Government would be very negative toward illicit growth. They don't want their country to become yet another country that has this huge illicit opium and heroin problem.

On the other hand, we know there are some problems in capabilities and in monitoring and that has to be worked on, so I am not sure what their capability would be in the face of that kind of phenomenon. So I would be concerned about that. The illegal aspect of this is a matter of concern to us.

Mr. HUGHES. I share your concern, and I am not saying it is an easy thing to deal with, and I recognize it is very complex, but the Indians have not made it a priority to get their house in order; that has not been a priority.

Mr. LEVITSKY. I am talking about the drug issue in general. In the last couple of years, I think they have, as many countries have around the world, tried to cope with a growing problem, increased their capabilities, changed a number of laws, made them harder, have taken a much stronger attitude against the whole drug problem in their country. They have been forced to do that because of

the addict population, because of this increasing traffic transit problem through their country.

But if I look around the world at countries that have the problem and the will and determination of the governments concerned, I would put India in a very high category in terms of what they have done.

Now, have they solved the problem? No; no country has. But are they more effective than they were a couple of years ago? Yes, much more so. Have they cooperated with us in terms of investigations and joint operations and that kind of thing? Yes. Do they have a new structure that seems to be better? It has to be filled in somewhat and strengthened. Yes, they do.

So I look at it, in a sense, in a very positive way in terms of where they are going and what they have done, and I don't want to leave the impression that, although we have this concern—and it is an open concern that we have expressed and we have expressed to them—that we don't think that India is doing a better job than they did before. I believe that is the case. There has been a lot of progress made in India, and that is a positive thing for us.

Mr. HUGHES. Well, I am looking at it not just from the standpoint of the stockpiling of opium gum in India, but I am looking at it across the board as well. I recognize that they have a very serious substance abuse problem, as every source country ends up becoming a major abuser country in addition to being a source country. India has serious problems in the whole range of areas where we are attempting to put strategies in place. Take the chemical-free zone that we attempted to set up at the Indian-Burmese border. How serious have the Indians been? Can you tell me?

Mr. LEVITSKY. Particularly in the legal area, in terms of particularly one chemical, acetic anhydride, which is the main chemical we are talking about here, they have strengthened their laws in this regard. Our assessment is that, thus far, the implementation of that has not progressed very far.

Mr. HUGHES. The fact of the matter is, as you know, Mr. Secretary, when we set up the chemical-free zone at the Thai-Burmese border, they turned to Indian sources. We began working with India in trying to set up a chemical-free zone, and it has been a mixed bag. We haven't seen very much enforcement at the border, and I realize it is a resource problem.

Mr. LEVITSKY. Burma is a big problem in both regards.

Mr. HUGHES. Burma receives a large supply of their acetic anhydride out of India.

So I agree, I think the Indians have done some things, but I don't think that they have made diversion of chemicals as well as opium gum a major initiative on their agenda.

Now I am happy that you are going to India to sit down with the Indians, and I trust you are going to talk to them about a whole host of issues. I am happy about that. I don't accept the proposition, however, that the Indians have gotten totally serious. Frankly, I view the 2,000 metric tons of opium gum as a major potential problem for us.

I also view the production of opium gum as a major problem. Is it your intent to talk to them about possibly converting opium poppy into poppy straw?

Mr. LEVITSKY. It is laid out in the report for them to see as well as for you to see, so this is certainly a subject that we will discuss with them.

Mr. HUGHES. The gentleman from Florida.

Mr. McCOLLUM. Thank you, Mr. Chairman.

I want to ask a question of both you gentlemen based upon what the Penick Corp.'s testimony before us is going to say—in other words, the written testimony we have—about Turkey. The president of the corporation, who is, I think, going to testify in a few minutes, is saying in his written statement that Turkey is engaged in irresponsible commercial behavior, at least with respect to Penick. He says that due to the harvest's serious drought problems in the last year, a poor supply of the straw was out there, and Turkey's stockpiles have been severely reduced, and the price of the concentrated straw they were told would increase by 40 to 50 percent, which was in violation of a contract they had with the Turkish producers. Is this something which you were familiar with, Mr. Levitsky? Are others having the same problem with Turkey?

Mr. LEVITSKY. We have heard these—and I am going to let Mr. Haislip talk about this a little more, but we have heard talk about price gouging and that kind of thing, and I believe there is a system for reporting that, particularly to the DEA, which is the agency which regulates and implements this law, so that if there are specific instances of that there is a way of reporting that.

Mr. McCOLLUM. Mr. Haislip.

Mr. HAISLIP. We meet regularly with our three manufacturers of this material, and we do receive reports from them, and the Penick Corp. has given me a similar type of report about their negotiations with the Government of Turkey, and I have made some inquiries of the Government of Turkey as to whether they are able to supply the U.S. market in the fashion that we have previously expected. They have assured me that they are.

Now I don't really, of course, precisely know what is occurring here. It may be that there is a serious problem, or it may be simply that there is some kind of business negotiation in process. Obviously, we never get involved in a business negotiation, because many, many things are said by both parties to a business negotiation, sometimes about each other, as a matter of fact, and not always complimentary entirely. So that might be what is occurring here as well.

I would just say this, and I think it has been said, that our policy of favoring these two traditional sources is based on two things: one, that they do produce an adequate supply for the U.S. needs. If they fail to do so, then that, of course, means that the policy needs to be reexamined.

The second thing is that they do the best they can to make a good faith and strong effort to control diversion, and if they fail to do so, then that requires reexamination. Those are predications of the policy.

But what is happening in this particular case with this particular company and their source, I don't know if it is a negotiation situation.

Mr. McCOLLUM. What Penick is saying is that Turkey has informed them that they would not likely be able to meet the con-

tractual commitments they made during the calendar year of 1990, and I guess that is yet to be seen technically.

Mr. HAISLIP. Yes.

Mr. MCCOLLUM. But if that were to occur, would it disturb you?

Mr. HAISLIP. It would disturb me, but, as I say, I have made some inquiries to see if there is a changed situation in Turkey that is something out of character with the past, and I have been told that there is not. I don't know. I mean we get told lots of things by lots of people for lots of reasons.

Mr. MCCOLLUM. I understand.

Well, thank you very much for commenting on it, anyway.

The problem we have a lot of times is that much of the testimony we get that would be interesting for you to comment on and we would hear from is going to come later, after you have gone. So I am just trying to give you a chance to comment on that.

Thank you.

Mr. HUGHES. Why don't we just pick up on that, because that is something that I had intended to get to eventually, and that is the prospect of market manipulation.

Now if I heard from one importer the suggestion that we may have a problem with supply, that would be one thing. But I have heard it from more one—and we only have three importers in this country. Because the 80-20 rule basically locks in the major supply to two countries, there is a tremendous potential for that manipulation. I am hearing it over and over again, which suggests to me that there probably is some substance to it.

Mr. HAISLIP. May I comment on it?

Mr. HUGHES. Sure.

Mr. HAISLIP. Of course, that is always a danger, and if it occurred I think we would want to react to it very sharply and very quickly once we knew that it occurred, but I would point out to you, as I said earlier, the price for this commodity has decreased over the past decade, has not increased, although the price for virtually every other commodity has increased in the world.

Mr. HUGHES. It is up now, isn't it?

Mr. HAISLIP. It is up over a previous year, perhaps it is, but I am speaking of the 10 years for which the policy has been in force. So we don't have any evidence that this has happened. If it is happening or does happen, we must react very severely. If the Indian Government doesn't act in good faith to deal with these problems that Secretary Levitsky has outlined, that has to be reacted to.

The policy is not something that is set in concrete and never can be changed or adjusted depending upon what is happening and what people's attitudes are, so that the concerns you have voiced are the concerns that we have here too.

Mr. HUGHES. Well, it apparently is happening. Something else is happening. Mallinckrodt, I believe, was required to take a supply of opium gum. They wanted the concentrated poppy straw, because their whole processing center is based upon the processing of opium straw. First of all, they didn't have the personnel; they had to bring some specialists in to assist them in setting up additional processing capability. They had a problem dealing with the byproducts, as I understand it. But they were forced, under the 80-20 rule, to resort to opium gum simply because there wasn't sufficient

supply of poppy straw available. What do you have to say about that? Is that something we should be encouraging?

Mr. HAISLIP. Let me comment.

Mr. HUGHES. I'm sorry, that was Penick, that was not Mallinckrodt.

Mr. HAISLIP. Yes, it was Penick.

Well, we register all of these companies every year, and part of the consideration is the issue of the state of the art and manufacture, and we have repeatedly had assurances from all of them, especially when they applied for registration—and in one case it was contested—that they have the capability to process all these narcotic raw materials. It would greatly surprise me if they did not, since prior to the emergency rule of the midseventies it was the only material that we permitted to be imported into the United States.

Now, you know, if it costs more to process opium than poppy straw, the reason for that is that poppy straw has already been processed. In other words, someone has already done the manufacturing on the poppy straw, and we get it in a form in which only a small part of the processing remains to be done. In the case of opium, we have to do the manufacturing as opposed to just the cleaning up of the material, and we have always had an industry that could manufacture drugs from raw materials, much like we manufacture automobiles from steel.

Mr. HUGHES. Is that a precondition?

Mr. HAISLIP. It has always been understood that they would have that capability to handle raw material.

Mr. HUGHES. But is that a precondition to licensure?

Mr. HAISLIP. I would say that it is under our policies. We have always understood that they would have that.

Mr. HUGHES. I would think, as a matter of policy, that since there is less chance of diversion from the concentrated poppy straw than from the opium gum, we would encourage the processing before it comes into this country, as a matter of policy.

Mr. HAISLIP. Oh, I see. You mean where it is produced in the fields?

Mr. HUGHES. As a matter of policy. Shouldn't that be our policy? I am asking a question.

Mr. HAISLIP. Well, I think this is the reason why we have indicated and the secretary has told you that we are going to explore this CPS production for India.

Mr. HUGHES. The gentleman from Pennsylvania.

Mr. McCOLLUM. No further questions, Mr. Chairman.

Mr. HUGHES. Well, thank you very much. I have no further questions.

Mr. Secretary, I want to tell you that I am very happy that you are on board, for any number of reasons, not the least of which is, you have the credentials, I think, to make a difference in this and many other areas, and I realize it has been a learning process the last few months, trying to find out as much as you need to know about the narcotics problem.

I didn't mean to suggest in any of my questioning that I am not very happy, because I am very happy, with the fact that you are on top of this issue. I just regret—I really do regret—that we sent a

signal that we are going to extend this program for 3 years. I would much have preferred a year; after you come back, review it, and make whatever changes we need to make to send signals at this time about some of the problems that we seem to have experienced in this whole area of concentrated poppy straw and opium gum.

In any event, I wish you well with your visit and your discussions.

Mr. LEVITSKY. Thank you very much, and let me say again that we don't have to wait for a year to come back and discuss this and give you some of at least our preliminary views after we have looked at this again after the trip, because I think that will also further refine my own thinking, and then I can discuss this with the other agencies involved.

Mr. HUGHES. And I am to take from that that if we need to revisit the whole question of the 80-20 rule 6 months from now, we will do that?

Mr. LEVITSKY. If the Congress wants us to do it, we will do it, certainly.

Mr. HUGHES. Thank you very much.

Our second panel this morning consists of representatives of the three U.S. manufacturing companies that are licensed to import and process narcotic raw materials derived from the poppy plant: Mr. Raymond Stratmeyer, who will be accompanied by Mr. Robert Angarola; Dr. Aris Christodoulou; and Mr. Lloyd Nystrom.

The first panelist is Mr. Raymond Stratmeyer, vice president of Johnson & Johnson International, of New Brunswick, NJ. Mr. Stratmeyer also serves as president of Noramco, Inc., of Wilmington, DE. He has formerly worked for Mallinckrodt and the Monsanto Co.

Mr. Stratmeyer is accompanied this morning by Mr. Robert T. Angarola, a member of the Washington, DC, law firm of Hyman, Phelps & McNamara, P.C. Mr. Angarola has served as legal adviser to the U.S. International Narcotics Control Board in Geneva, Switzerland, and as General Counsel to the White House Office of Drug Abuse Policy. In 1978, he was Assistant Director of the White House Domestic Policy Staff handling health and drug issues.

Our next panelist is Dr. Aris P. Christodoulou, president, chief executive officer, and chairman of the board of Penick Corp. of Newark, NJ. He is also president and director of Mayfair Pharmaceutical, Inc., and director of Mayfair Capital Partners, Inc. He has worked for Merrill Lynch, Lehman Brothers, and Blyth, Eastman, Dillon & Co. and holds a Ph.D. in chemical engineering.

Our final panel member is Mr. Lloyd W. Nystrom, business director for medicinal narcotics with the Mallinckrodt Specialty Chemicals Co. of St. Louis, MO. Mr. Nystrom has been active in the bulk medicinal narcotics business with Mallinckrodt since 1976 and before that with the Upjohn Co.

Gentlemen, we have your statements which, without objection, will be made a part of the record. We hope you can summarize for us.

Thank you.

Why don't we begin with you, Mr. Stratmeyer.

**STATEMENT OF RAYMOND J. STRATMEYER, VICE PRESIDENT,
JOHNSON & JOHNSON INTERNATIONAL, NEW BRUNSWICK, NJ**

Mr. STRATMEYER. Mr. Chairman and members of the subcommittee, in addition to the responsibility for Naramco, the managing director of Tasmanian Alkaloid reports to me. This company grows and processes the opium poppy on the Australian island of Tasmania, and it sells these products around the entire world. So I feel we do have a worldwide perspective.

The three U.S. suppliers that are at the table primarily buy their raw materials from India, Turkey, France, and Australia with, of course, 80 percent from India and Turkey, 20 percent maximum from France and Australia.

I would like to mention that opium is a distinctly different product than CPS. There was talk about that earlier, but opium is roughly 20 percent valuable alkaloids and about 80 percent gums, tars, agricultural debris; it is difficult to process. CPS, on the other hand, is 80-20 the other way—a different 80-20—80 percent good alkaloids and 20 percent things you have to get rid of.

The opium contains morphine, codeine, thebaine, and noscapine. Noscapine is not an essential drug in the United States, and, really, we don't feel it is an essential drug in the world. Turkey's CPS contains only morphine with traces of codeine, and French and Australian material contains morphine, codeine, and thebaine.

I would like to talk about diversion issues. First, the three key CPS producers—Turkey, France, and Australia—have excellent records, and all at present have very good inventory control. Turkey had one problem while they were getting organized. We hope that they have learned how to control inventory. Right now, they have told us they are essentially out of inventory.

Mr. HUGHES. I'm sorry, what?

Mr. STRATMEYER. Turkey has told us that they are really out of inventory. They have told us that they are exploring buying 100 tons of Indian opium that they would process. They cannot supply that to the States, but they could supply it to other customers, freeing CPS for the States. But whether they can do this or not, I think, is very doubtful. It is a very difficult product to process.

India, in contrast, has significant diversion, has excess inventories, and they have certainly not managed their system very well. They have many farmers, many small plots, and low quotas. By low quotas I mean a farmer must produce a certain amount per hectare, but he can produce more than that per hectare. Most farmers can, which means they have a built in way to have some material available to sell to the illicit market, where the price is 10 times as much. That, to me, is not a sensible system. So they don't control inventories, they don't control diversion, and yet the 80-20 rule favors India.

From a commercial viewpoint, opium and CPS are not fungible, you can't interchange them, because of the differences I talked about, and they should not be grouped together under the 80-20 rule. The current situation—what is going on right now—is a good example. Turkey is out of CPS, so we must buy opium to fill up the 80 percent of our needs that Turkey cannot supply. We don't want that much opium. The result is, we have an inventory buildup of

noscapine and thebaine, we have more pollution because opium is much dirtier material, we use more manpower, and in some cases—not in this case—it could mean higher cost. So we are rewarding India for violating the spirit of the Single Convention. We simply think this is not right.

However, opium is needed because there is not sufficient raw material to meet the world's needs without it. It takes years to grow plants, to process material, to build adequate inventories, and right now the world supply is based upon India producing opium, and to ban opium would not be an answer; it would throw us into a shortage situation.

The 80-20 rule had three objectives: Prevent proliferation of supply. I might say, this really does not fit the 80-20 rule, because anything we buy the DEA must approve, and there is no problem of controlling supply sources. The second was to eliminate excess supply, and of course with India's inventory, it has obviously failed here. It has failed in reducing diversion because India has considerable diversion.

Now what do we recommend? If we were the decisionmaker, we would recognize opium as being different than CPS. There is one supplier; if you want opium, India has a monopoly. We would not require that any company be required to buy from India; you could if you wanted to, but you would not be required to do so.

In addition, we think under this scenario that demand for Indian opium would slowly decrease. It has decreased in the past, because CPS is a more attractive material. In the light of diversion of Indian opium maybe a brief time would be given India to bring their house under control. There has to be time to allow the world to accommodate to reduced usage of opium.

We would also guarantee Turkey some percent of all CPS. In other words, opium would be free, but all CPS would be controlled, with Turkey having a certain percent allowed that we would be forced to buy from them, provided they were competitive in price; that would be the only caveat.

However, we recognize that there are a lot of other points of view and it is a complex issue. There are trade negotiation issues, there are Single Convention issues, international relations, commercial, diversion, and so on, so we recommend that the DEA call a hearing where everyone can be heard and we get a broad-based decision that balances supply and demand, eliminates diversion, provides stable supply, competitive prices, and, of course, makes the world abide by the Single Convention. These are the things the 80-20 rule has not done.

[The prepared statement of Mr. Stratmeyer follows. The attachment to Mr. Stratmeyer's statement, "Economic Analysis of U.S. Narcotic Raw Material Policy," may be found in app. 3, p. 116.]

PREPARED STATEMENT OF RAYMOND J. STRATMEYER, VICE PRESIDENT, JOHNSON &
JOHNSON INTERNATIONAL, NEW BRUNSWICK, NJ

LICIT IMPORTATION OF OPIATES

Testimony of Raymond J. Stratmeyer
Vice President, Johnson & Johnson International

Before
House Subcommittee on Crime

February 27, 1990

SUMMARY

Johnson & Johnson (J&J) is one of the three U.S. importers of narcotic raw materials. It uses opium and concentrate of poppy straw (CPS) to make drugs such as codeine and morphine. J&J is also the owner of Tasmanian Alkaloids which grows and processes the opium poppy on the Australian island of Tasmania where it produces CPS.

U.S. manufacturers import opium from India and CPS from Turkey, Australia and France. Opium and CPS are very different commodities. Opium is more easily diverted, is more difficult and costly to process, and has a greater environmental impact than CPS. Opium is preferred only when the demand for alkaloids other than codeine and morphine is high or when opium is significantly cheaper than CPS. Given a free market and adequate supply, J&J would meet most of its needs through CPS, although it would still buy some opium to ensure raw material availability.

When Turkish CPS is unavailable, a Drug Enforcement Administration (DEA) regulation, the "80/20 rule", forces J&J to buy opium from India when it would prefer to buy CPS from Australia or France. There is widespread opium diversion at the farmgate in India and increasing manufacture of heroin. There are no such control problems in countries producing CPS. Thus, because of the 80/20 rule, the U.S. directly supports an Indian government subsidy that has been encouraging the overproduction of opium.

Turkey has not been the source of illicit narcotics since, at U.S. urging, it banned opium production in 1972. In contrast, current U.S. regulation is actually promoting continued opium production in India by requiring manufacturers to buy a commodity they do not want from a country that cannot prevent diversion. This undercuts international drug control efforts.

J&J believes that the U.S. should support Indian efforts to control opium production, reduce its large stockpile and find alternate crops for farmers now cultivating the opium poppy. At the same time, U.S. manufacturers should have the flexibility to buy the narcotic raw materials they want from countries that maintain proper controls over production. DEA should immediately begin a formal administrative review of (1) the abolition of the 80/20 rule and (2) means of helping India prevent diversion.

Mr. Chairman, members of the Committee:

My name is Raymond J. Stratmeyer. I am a Vice President of Johnson & Johnson International (J&J), based in New Brunswick, New Jersey. I am also President of Noramco, Inc., which processes opium and concentrate of poppy straw (CPS) to make drugs such as codeine and morphine in Wilmington, Delaware. In addition, the Managing Director of Tasmanian Alkaloids reports to me. This company grows and processes the opium poppy on the Australian island of Tasmania and produces concentrate of poppy straw, as well as a wide variety of narcotic alkaloids and specialty chemicals for worldwide sale. Before joining J&J, I was General Manager of Mallinckrodt Medicinal Narcotic Division, serving in that capacity during the opium/CPS shortage of the 1970s.

I am accompanied by Robert Angarola, outside counsel to J&J, who has served as an attorney with the United Nations International Narcotics Control Board and General Counsel of the White House Office of Drug Abuse Policy.

We would like to present Johnson & Johnson's analysis of the world narcotic raw material situation and the effect current U.S. regulatory policy has had on our ability to purchase needed opiate raw materials. We believe that existing regulation is negatively affecting us commercially and is contributing to opium diversion in India.

NARCOTIC RAW MATERIAL IMPORTS

There are two distinct forms of narcotic raw material now being imported into the United States: gum opium from India and concentrate of poppy straw from Turkey, Australia and France.

Opium

Opium is a crude, morphine-rich latex which is harvested by scraping the sap from lanced capsules of the poppy papaver somniferum L. Opium contains four commercially important alkaloids: morphine, codeine, noscapine and thebaine. From a manufacturer's perspective, opium is a much more difficult raw material to process than CPS. It takes many more steps and costs more money to produce useful end-products. Opium processing also requires the use of a greater amount of solvents which have an environmental impact. Opium is a unique product, with its own market, and is not available from any other country than India.

The system used to produce opium is significantly less secure than that used to make CPS. Diversion of opium occurs at the farmgate. Illicit traffickers produce morphine-base and heroin in multi-ton quantities from gum opium.

Concentrate of poppy straw

Concentrate of poppy straw is produced by harvesting and processing unlanced poppy capsules. This results in a product that contains morphine and codeine. Australian and French CPS also contain thebaine, although Turkish CPS does not. As imported into the United States, CPS can contain up to 80% pure

- 3 -

morphine. It is much easier and cheaper to process and has less of an environmental impact than opium.

This system used to produce concentrate of poppy straw is significantly safer than opium production for drug control purposes. Unlike opium, which can be readily converted into heroin, CPS requires more sophisticated processing before it can be transformed into an abusable substance. The unaltered poppy capsules used in CPS production are low in morphine content (e.g., 0.3% to 0.5% in Turkey) and are very bulky. After arriving at the conversion factory, processors impose tight controls over manufacture, and diversion is not an issue.

DEMAND FOR OPIUM AND CONCENTRATE OF POPPY STRAW

For the reasons presented above, J&J views gum opium and concentrates of poppy straw as very different commodities. The relative demand for opium and CPS depends on market forces that are linked to a great extent to projected sales of the alkaloids noscapines and thebaines and not to sales of the more commonly known narcotics, morphine and codeine. Absent regulatory controls or significant price differentials, our Noramco subsidiary will purchase CPS when we want to produce codeine or morphine. We will buy thebaine-containing CPS if we need thebaine. Because of additional costs, processing problems and environmental concerns, we will only use opium when we want to obtain noscapines or additional thebaine supplies or when price differentials make it attractive.

- 4 -

The medical use of noscapine has decreased over the past few years, thereby reducing the demand for opium and making CPS even more attractive to processors. There are sufficient supplies of thebaine to meet demand. Because of limitations on increasing the amount of CPS Australia and France can produce, Turkey is assured a large percentage of the U.S. narcotic raw material market. However, due primarily to a crop failure and high sales, there is now a shortage of Turkish CPS.

Current market conditions would lead J&J to meet most of its narcotic raw material needs in the form of concentrate of poppy straw from Turkey, Australia or France, although we would still buy some opium to ensure raw material availability. Current U.S. regulation is not allowing us to do this.

THE 80/20 RULE

Drug Enforcement Administration (DEA) regulations limit narcotic raw material imports to seven countries^{1/} and require that at least 80% of these imports have as their original source Turkey and India (the "80/20 rule").^{2/} A 1979 United Nations Commission on Narcotic Drugs resolution triggered the U.S. decision to restrict narcotic raw material imports. According to the language of that resolution, one of the principal factors given for urging governments to give preference to traditional

1/ Turkey, India, Yugoslavia, France, Poland, Hungary and Australia. 21 C.F.R. §1312.13(f) (1989).

2/ 21 C.F.R. §1312.13(g) (1989).

suppliers (i.e., India and Turkey) was "their contributions in the maintenance of effective control systems."^{1/} Three DEA Federal Register notices relating to the 80/20 rule show that the regulation's purpose was to (1) limit the number of producer/exporter countries, (2) reduce excess supplies in traditional producer countries, and (3) prevent diversion.^{4/}

In 1981, when the government adopted the 80/20 rule, there was little understanding of the significant differences between Indian opium and concentrate of poppy straw as narcotic raw materials. The rule combines them for regulatory purposes on the assumption that, if a U.S. manufacturer cannot obtain one, it can easily substitute the other to produce narcotic drugs. It is now apparent that they are not fungible. The 80/20 rule does not recognize that, as now, when demand for noscapine is low and Turkish CPS is in short supply, a U.S. processor would want to purchase more than 20% of its needs from Australia, France or the other authorized CPS exporters.

As noted, the three goals of the 80/20 rule were to limit the number of supplier countries, reduce opiate stocks and prevent diversion. It has helped accomplish the first goal since only four of the seven authorized countries are now exporting to the United States and no new producers have entered the market.

^{1/} 44 Fed. Reg. 33695, 33696 (June 12, 1979).

^{4/} 44 Fed. Reg. 33695 (June 12, 1979), 45 Fed. Reg. 9289 (February 12, 1980), 46 Fed. Reg. 41775 (August 18, 1981).

Therefore, there is no need to change 21 C.F.R. §1312.13(f) which limits imports to seven countries. However, it is clear that, at least in the case of India, it has been a total failure in reducing stocks or preventing diversion.

REDUCTION OF OPIUM STOCKS

India (and in the past, Turkey) has planned opiate production with little regard to current or future market demand. For example, according to DEA statistics, India reduced its opium stocks significantly in 1987-88 due to a temporary increase in demand for noscapine. That same year, instead of maintaining the same level of production in order to keep the stocks at the reduced level, it increased the number of licensed cultivators by 25%, from 129,000 (estimated) to 160,909.^{5/} Not surprisingly, the next year there were stock increases. This refusal to gear production to market demand has led to the accumulation of stocks of over 2,300 tons of Indian opium; these stocks continued to increase in 1988, the latest year of record,^{6/} although recent shortfalls in Turkish CPS availability will probably lead to some reduction.

Current stocks could meet the world opium demand for several years. Unlike Australia and France which set production levels

5/ Report to Congress: Licit Opium Review, Department of State, Bureau of International Narcotic Matters, and Department of Justice, Drug Enforcement Agency [sic], January 1990, 33. ("Licit Opium Review.")

6/ Narcotic Drugs: Statistics for 1988, International Narcotics Control Board, E/INCB/1989/2, Vienna 1989, 34.

to market demand, state subsidies have not made inventory control a high priority in India.

Both the Indian and Turkish governments subsidize the production of narcotic raw materials. At present prices, both these governments lose money on every kilogram of opium or CPS they sell. (Recently, due to fiscal considerations and the shortage of CPS, Turkey has raised the asking price of its product by 70%. U.S. manufacturers are currently paying a premium for Turkish CPS because of the 80/20 rule. If this aggressive price increase is sustained in the marketplace, it will minimize, although not eliminate, Turkey's losses.) Direct subsidies, and indirect subsidies such as that offered by the United States in the form of the 80/20 rule, have encouraged Indian farmers to continue to produce opium at uneconomic levels without regard to reduced demand for this commodity. At the same time, there are several reports of increasing opium diversion from licit production in India.

DIVERSION OF OPIUM

According to a 1989 State Department report, India's licit opium cultivation has become "an important source of illicit opium and heroin."⁷ That report estimated that a possible 60 to 120 tons of Indian opium were diverted in 1988,⁸ equivalent to 8

7/ International Narcotics Control Strategy Report, U.S. Department of State, March 1989, 142.

8/ Id.

- 8 -

to 16 tons of heroin. Interpol reports that New Delhi and Bombay are major heroin transit points.^{9/} A recent report to the Congress affirms that India remains a significant heroin transit/transshipment country, with

unconfirmed reports of crude opium labs near the licit growing areas. A recent New Delhi Country Office investigation also revealed the existence of a heroin lab in the Bombay area that produced high quality heroin for export to the United States. Local newspaper articles have reported the seizure of heroin laboratories around the licit poppy growing areas. In spite of all this evidence, the official government position is that there are no heroin labs in India.^{10/}

This report also states that the number of morphine-base laboratories in India seems to be increasing and U.S. intelligence indicates that "an increasing amount of opium is being diverted from licit production."^{11/} Licensing over 160,000 farmers to produce opium on smaller and smaller plots of land has fostered diversion at the farmgate. This is not surprising when government prices for licit opium are \$14-16 per kilogram of opium produced while the current black market price for opium at the farm level is \$150 per kilogram.^{12/}

Interpol reports that Nigerian traffickers are transporting multi-kilogram quantities of narcotics from India/Pakistan to

9/ Opiates, the International Scene 1988-89, Drugs Sub-Diversion, ICPO/Interpol, October 1989, 4 (self-numbered). ("Interpol Report.")

10/ Licit Opium Review at 36.

11/ Id. at 37.

12/ Id.

African capitals for onward shipment to Europe and the United States. New York remains the primary point of importation and distribution.^{13/}

Representatives of the government of India have reportedly stated that, if there is any diversion of licitly produced opium, it is all consumed domestically. However, according to U.S. government reports, India is failing to maintain adequate controls over licit production and allowing the diversion of large amounts of opium, a portion of which is probably reaching Philadelphia, New York and other parts of the East Coast of the United States.^{14/}

The problems associated with opium diversion and heroin manufacture in India should be contrasted with the actions Turkey took in switching from opium to CPS production in the 1970s.

In the late 1960s, "the great majority of heroin entering the United States was produced from the illicit processing of opium harvested in Turkey from legitimately cultivated Papaver [somniferum]."^{15/} At the urging of the U.S. government, Turkey undertook the politically difficult step of banning opium production in 1972. Two years later Turkey began instituting the CPS method of production. Since that time, there have been no

13/ Interpol Report at 8 (self-numbered).

14/ Heroin Situation Report, European/Asian Drug Trafficking Unit, Federal Bureau of Investigation, reprinted in Cong. Rec., July 20, 1989, S8475.

15/ Licit Opium Report at 18.

- 10 -

reports of Turkish source heroin entering illicit channels. This experience of extremely tight controls over CPS production has been replicated in Australia and France, which have had no problems of opiate diversion. U.S. policy was aimed at halting opium production in Turkey. Today, our policy, as embodied in the 80/20 rule, is encouraging and actually supporting Indian opium production.

EFFECT OF THE 80/20 RULE

A 1989 House Foreign Affairs Committee staff report concluded that the 80/20 rule had not achieved its intended purpose of preventing diversion of opiates to the illicit market and had probably encouraged inefficient state-subsidized production practices in Turkey and India.^{16/} Contrary to this finding, the Licit Opium Review states that "the '80-20 Rule' has met its stated objectives"^{17/} However, that Review does not explain how the 80/20 rule has advanced any of its objectives as they relate to diversion control and stockpile reduction. To the contrary, the Review shows that the drug control situation in India has worsened since 1981 when the rule was adopted, and stocks have increased.

-Based on available facts, Johnson & Johnson believes that increased opium diversion and changing commercial interests

^{16/} U.S. Licit Opium Imports: Foreign Policy Issues, Report of a Staff Study Mission, House Committee on Foreign Affairs, 101st Cong., 1st Sess., May 1989, 12.

^{17/} Licit Opium Review at 23.

require that the 80/20 rule be repealed or significantly modified for the following reasons:

1. Diversiion problems

As shown by the U.S. government and Interpol reports cited above, the 80/20 rule has clearly not prevented diversion of Indian opium. It is in fact contributing to this problem.

2. Stockpile reduction

According to the International Narcotics Control Board, stocks of Indian opium amounted to approximately 2,300 tons in 1988.^{18/} This is an increase in stocks over 1987 levels. This quantity would meet world opium requirements for over three years. Clearly, the 80/20 rule has not been effective in reducing opium supplies.

3. U.S. subsidizing opium production and diversion

Current U.S. regulatory policy is completely at odds with the steps the government took in the early 1970s to halt Turkish opium production and diversion that was resulting in heroin abuse in the United States. At that time, the U.S. worked aggressively to convince Turkey to ban opium production and offered assistance to that end. Using its own resources, Turkey took that politically courageous step and, since that time, has not been the source of illicit narcotics. This is one of the few success stories the international drug control system has ever witnessed.

^{18/} Narcotic Drugs: Statistics for 1988. International Narcotics Control Board, E/INCB/1989/2, 34.

- 12 -

The 80/20 rule takes a diametrically different approach to opium diversion in India. Instead of encouraging the Indians to ban or restrict production, the DEA regulation is forcing J&J and other importers to buy Indian opium they do not want, thereby actively subsidizing continued opium production and, ultimately, diversion.

The only force that will reduce Indian opium stocks and ensure a balance between supply and demand is market discipline. If India lost that part of the U.S. market attributable to the working of the 80/20 rule, it would have to absorb the full cost of subsidizing overproduction, rather than just the difference between the export price and the farm price. That added cost would give India an incentive to seek alternative uses for the land now devoted to growing poppies. It might also help the government recognize the economic reality that, today, opium is a less desirable commodity than CPS, leading it to reduce or suspend production.

The Licit Opium Review states

[i]t is difficult to speculate on whether or not the Indian government would consider a further significant reduction of the area under cultivation or a reversal in the increases which have occurred since the mid-1980s in the numbers of licensed farmers. It is clear, however, that further reduction cannot be made under present conditions without increasing economic hardship in the growing areas which would entail a high political cost to the government.¹⁹

19/ Licit Opium Review at 34.

The same argument can be made for a farmer in the Golden Triangle or in Bolivia, except that he does not have the shelter of a licit product.

As the example of Turkey demonstrates, curtailing drug diversion requires decisive political action that accepts certain costs as the price of achieving the greater benefit of disrupting illicit drug trafficking. Turkey's success was due to a willingness to act, not to the suspension of market forces brought about by regulations such as the 80/20 rule.

Recent developments in Latin America show that governments pay a high political price indeed when, for economic reasons, they do not take effective action against diversion and illicit drug production. If the government is receptive, the international community should assist India in its drug control efforts. The 80/20 rule, however, makes any offers of assistance pointless by eliminating India's economic incentive for accepting them.

In considering the adoption of the 80/20 rule, a DEA Administrative Law Judge stated that "the United States should not purchase narcotic raw materials or otherwise encourage production by countries that may not be capable of maintaining adequate control against diversion."^{20/} Present implementation of the 80/20 rule ignores this counsel. The effect of the rule is

^{20/} Report to the Administrator, In the Matter of Proposed Limitations on Imports of Narcotic Raw Materials, DEA Docket No. 80-18, January 16, 1981, 37-38.

to actively encourage production of opium in India, thereby contributing to the diversion problem.

4. U.S. vulnerability to monopolistic price increases

As the attached economic analysis of U.S. narcotic raw material policy demonstrates, the 80/20 rule leaves the U.S. in a vulnerable position by turning U.S. importers into captive buyers. This is particularly true if demand for Indian opium continues to decrease significantly. Since it is assured up to 80% of the narcotic raw material market, Turkey could choose to set its CPS prices with the aim of maximizing profits in the United States. J&J and other manufacturers would have to pay these prices since the 80/20 rule would prevent them from seeking a significant quantity of less expensive CPS elsewhere.

The U.S. is subject to supply shock, just as when OPEC raised the price of oil unexpectedly during the 1970s. So long as we have limited sources of supply -- in this case by our own regulation -- we will remain vulnerable. The 80/20 rule perpetuates this vulnerability by preventing alternative sources of supply, even quite secure ones, from serving U.S. importers because they are limited to a total of 20% of the market.^{21/}

ASSISTANCE TO INDIA

With modification of the 80/20 rule, the United States should work with other governments and the United Nations to

21/ Ordovery, J. and Shapiro, C., Economic Analysis of U.S. Narcotic Raw Material Policy, March 1989, 14 (attached).

- 15 -

support Indian efforts to control opium production, reduce stocks and find alternate crops for some of the farmers now cultivating the opium poppy. The World Health Organization and the International Narcotics Control Board have recently called for greater use of opiates to treat conditions such as cancer pain in developed and developing countries.^{22/} Opium stocks could be used to help meet this need. It has also been suggested that the U.S. purchase a significant portion of the stocks for the National Stockpiles Center at the Department of Defense. If this occurs, it should be linked to a reduction in the hectareage devoted to poppy cultivation, the imposition of effective diversion control measures and the limiting of future production to market demand, less needed draw-downs from the stockpile.

CONCLUSIONS

The above facts support the following conclusions:

- Gum opium and concentrate of poppy straw are entirely different commodities from a manufacturer's perspective.
- At present opium is a less desirable narcotic raw material for the processing of narcotic drugs, although some is still required to meet medical needs.
- India is facing significant drug abuse and drug trafficking problems, including:
 - increasing opium diversion and heroin manufacturing;
 - high and increasing levels of domestic drug abuse;
 - its becoming a major international narcotic trafficking center.

^{22/} Demand for and Supply of Opiates for Medical and Scientific Needs, Special Report of the International Narcotics Control Board, E/INCB/1989/1/Supp., Vienna 1989.

- 16 -

- . The 80/20 rule has not reduced opium stocks nor prevented diversion to the illicit traffic.
- . The 80/20 rule makes the U.S. vulnerable to monopolistic price increases.
- . The 80/20 rule is forcing J&J and other U.S. manufacturers to buy unwanted opium, thereby providing direct U.S. support for the Indian government subsidy that has been encouraging the overproduction of opium, some of which is being diverted.
- . As long as opium is produced under current controls, there will be significant diversion to the illicit market and increased production of heroin in India.
- . The action of the U.S. government in supporting the Turkish ban on opium production resulted in the elimination of Turkish-source heroin from the United States and elsewhere.
- . It is in the interest of the international community to help India deal with its drug control problems, if the government is receptive.

RECOMMENDATIONS

1. DEA should immediately begin the administrative process to review all aspects of the 80/20 rule, including public health, law enforcement, commercial, regulatory, trade and competitive issues.
2. At the conclusion of this process, opium should be removed from the operation of the 80/20 rule, thereby allowing manufacturers to buy the quantities of this commodity they need when they need them.
3. The 80/20 rule should be repealed or significantly modified to allow manufacturers to purchase CPS from Turkey, Australia and France in the quantities they need, at competitive prices.
4. The U.S. government, working either bilaterally or multilaterally, should work with India to reduce its drug abuse and drug trafficking problems as well as encourage efforts to scale back opium production to market demand while imposing adequate controls against diversion.

- 17 -

5. The U.S. should consider means of reducing opium stocks through direct purchase from India for the manufacture of medically needed opiates for developing countries or for addition to the National Stockpiles Center at the Department of Defense.

* * * * *

The Congress should urge DEA to publish, as soon as possible, a Notice of Proposed Rulemaking aimed at (1) determining whether to modify or repeal the 80/20 rule and (2) identifying means of assisting India in their drug control efforts. This will allow interested parties to provide the agency with information supporting or opposing changes to the rule and, more importantly, ensure that U.S. policy is not unwittingly contributing to international drug control problems. We cannot wait another three years, as the Licit Opium Review has proposed, to begin this process which will, in itself, take two to three years to complete. Congress should direct the Administrator of DEA to analyze and report specifically on how the 80/20 rule has achieved the goals of preventing drug diversion and ensuring a balance between supply of and demand for the two narcotic raw materials, opium and concentrate of poppy straw.

We thank you for the time and attention you have given to this matter and stand ready to answer any questions you might have.

Mr. STRATMEYER. Bob, would you like to make a statement?

Mr. ANGAROLA. Mr. Chairman, with your permission, could I make two quick points?

Mr. HUGHES. Sure. Why don't you identify yourself.

STATEMENT OF ROBERT T. ANGAROLA, ESQ., HYMAN, PHELPS & McNAMARA

Mr. ANGAROLA. My name is Robert Angarola. I am outside counsel to Johnson & Johnson. I was formerly with the White House Drug Policy Office, and I first entered the Office in 1972 when the Turkish opium ban was being considered.

At that time, as has been mentioned, the U.S. Government brought a great deal of pressure and offered a great deal of resources to Turkey to stop opium production. Turkey never accepted those resources, as it turned out, but they did stop production. The policy of the United States was quite clear: Opium production in Turkey under the conditions that production existed was leading to diversion and that should be halted.

I looked at the policy in 1990, 18 years later, where we have an opium producing country, India, having very similar diversion problems that we saw in Turkey, maybe not with as much of a direct linkage to the United States as the Turkish-French connection, but clearly experiencing major diversion problems.

What is U.S. policy today? As Mr. Stratmeyer has described, we are forcing our manufacturers to buy opium from India. India is already subsidizing production. U.S. regulation provides another subsidization, a U.S. manufacturer subsidization, for India to continue production. My belief is that the 80-20 rule is encouraging India to continue overproduction. If market discipline were imposed, we would assume that India would meet its treaty obligations and control the production that does go on and limit the number of farmers and the amount of hectareage devoted to that production. So I think there is a definite drawback of having the 80-20 rule in place.

A second point goes back to the 3-year proposal from the State Department. It was interesting—I don't know if you read Meg Greenfield today in the Washington Post, but I think there is a very telling quote there. It says, "One of the wonderful fringe benefits of the great political uprisings and reversals around the world that have characterized the past 6 months is that they have so confounded Washington's own way of doing things and unclothed so mercilessly our best kept secret. It is that, basically, nothing is ever supposed to happen in the sense of actually getting done. Things are meant to be worked on, and on, and on, and on, but never, God forbid, completed."

The proposal to wait 3 years is not in actuality 3 years. In order to change the 80-20 rule, the administrative process has to be completed. Typically, it takes anywhere from 2 to 3 years. So what we are saying is, let's not wait 3 years, let's wait 5 to 6 years, before any administrative change is made in 80-20. Now, of course, the Congress could act before that time.

So our proposal is, let's get moving, let's have a DEA administrative hearing commenced. DEA is one of the best and most effective

agencies I know, and I have been in this area for 18 years; they can get things done. But the process has to begin, and I think that message would be the clearest statement that we could send to the Indians and the rest of the world that we do take the problem seriously.

Thank you.

Mr. HUGHES. Mr. Stratmeyer, any more?

Mr. STRATMEYER. That is all, Mr. Chairman.

Mr. HUGHES. Thank you.

Dr. Christodoulou, welcome.

STATEMENT OF ARIS P. CHRISTODOULOU, PH.D., PRESIDENT, PENICK CORP., NEWARK, NJ, ACCOMPANIED BY JOSEPH M. BAORTO, VICE PRESIDENT, COMMERCIAL OPERATIONS

Dr. CHRISTODOULOU. Thank you, Mr. Chairman and members of the subcommittee.

Before we start, with your permission, I was hoping that I could get Mr. Joe Baorto, who accompanied me today, to join us at the table.

Mr. HUGHES. Sure.

Dr. CHRISTODOULOU. I don't want him to sit in my lap, so I wonder—

Mr. HUGHES. Just bring a chair up.

Dr. CHRISTODOULOU. Mr. Baorto—I will briefly introduce him since he is not on the program—is vice president of commercial operations for Penick Corp. and is our resident expert on matters of importation of narcotic raw materials, having, been involved in this activity for over 25 years. I personally consider him second to none in the industry in this role, and he has a historical perspective that has been valuable to me. I am a relative newcomer at this, having been in my present position less than a year.

Mr. HUGHES. We welcome him.

Dr. CHRISTODOULOU. Mr. Chairman, I would like to begin by stating that over the years we have cooperated and collaborated with the DEA in its concerns. However, we are a commercial company, and my focus today is mainly a commercial one, and I am going to be directing my statements that way.

From our perspective, going back in history, we viewed the 80-20 rule as designed principally to encourage the use of CPS from Turkey, which was at that time, in 1981, coming onstream with its new processing plant following the period of the opium production ban and the shortage that we spoke about earlier.

Penick Corp. fully supported the 80-20 rule as being essential at that time to help Turkey establish its position to sell CPS in the U.S. market. We have since supported Turkey in this endeavor to the best of our ability not only by purchasing CPS from this source but also by collaborating with Turkey, helping it to produce a quality product that would meet the quality standards set by the FDA of the United States.

In this period of time, in addition to its sales of CPS to the United States, Turkey made inroads in other world markets both with its CPS as well as with its derivative products, codeine and morphine. It is our opinion that Turkey no longer needs this com-

mercial protection in the United States for its output. We also believe that Turkey's apparent success in these other world markets may have encouraged the irresponsible commercial behavior that we are currently experiencing with this supplier.

To illustrate what we have seen, Penick officials were advised last year by representatives of the Turkish Opiates Board, TMO, that due to serious drought and the poor poppy harvest in 1989, Turkey would not be able to meet its contractual obligations for CPS in 1990. We later learned from INCB officials and from their statistics, that Turkey's stockpile had been severely reduced.

Penick has a contract with TMO which we entered into in late 1988 to purchase several tons of CPS for the balance of 1989. The TMO representatives assured us in a meeting that we had with them in May 1989, that they would honor that contract. Shortly after that meeting, we were informed that the price of our contracted CPS went up drastically, by 40 to 50 percent, which we consider a clear breach of TMO's contractual obligations to Penick.

Since then, we have brought this matter to DEA's attention and requested their help in helping us obtain these contracted quantities. So far, as of this moment, we have had no resolution of this matter. Failing that resolution, we believe some type of short-term emergency relief would be in order to permit us to make up this deficiency on the quantity defaulted upon by TMO from other sources.

Penick believes that at this time a gradual increase in the quotas be allowed from nontraditional sources. This would give the U.S. importers the needed flexibility and protection against such sudden shifts in quantities and prices that could be dictated by traditional sources to the U.S. importers. We have stated this position on previous occasions in Washington in recent years. We now advocate, as we have in the past, an initial change in the percentage allowed to be imported from nontraditional sources from 20 percent to 30 percent. This first step should be followed, in our opinion, by yearly reviews designed to adjust for possible supply anomalies in the producing countries.

This approach of gradual change in the 80-20 rule would allow normal supply/demand market forces to be the key control for the production of narcotic raw materials. Further, we firmly believe that the total elimination of the 80-20 rule, or even a major change in one step—say, to 50-50—would not be advisable at this time. This radical change would, in our opinion, create confusion and potential production and supply imbalances in the growing countries for the narcotic raw materials as well as create an unfair economic advantage which would benefit one of our U.S. competitors that has a direct link to nontraditional sources of these narcotic raw materials via subsidiary operation.

We believe, Mr. Chairman, that our position is reasonable, realistic, and consistent, with what we see in the marketplace.

That concludes our statement, and I will be pleased to answer any questions.

Mr. HUGHES. Thank you, Dr. Christodoulou.

[The prepared statement of Dr. Christodoulou follows:]

PENICK

CORPORATION

158 Mt. Olivet Ave., Newark, New Jersey 07114 • Telephone: (201) 621-2800 • Telex: TRT 178077
FAX: (201) 621-2816 • Cable: PENICKDRUG

SUMMARY OF STATEMENT OF PENICK CORPORATION

Presented to The Sub-Committee on Crime
of the House Committee on the Judiciary

February 27, 1990

Penick Corporation is one of three U.S. manufacturers licensed to import and process Narcotic Raw Materials (NRM) derived from the Papaver Somniferum plant, into finished bulk opiate pharmaceuticals.

Penick Corporation believes that, at this time, a gradual increase be allowed in the 20% quota from Non-Traditional Sources for NRM under the "80/20 Rule". This would give the U.S. importers needed flexibility and protection against sudden shifts in quantities and prices dictated by the Traditional Sources to the U.S. importers.

We now advocate, as we have in the past, an initial change in the percentage allowed to be imported from Non-Traditional Sources from 20% to 30%. This first step should be followed by yearly reviews designed to adjust for possible supply anomalies in the producing countries. This approach of gradual change in the "80/20 Rule" would allow normal supply/demand market forces to be the key control for NRM production.

The reason for our position is, on one hand, Turkey's commercial success in the world markets and accordingly the lack of present need for commercial protection in the U.S., and, on the other hand, Turkey's irresponsible commercial behavior and recent breach of its contractual supply obligations.

Further, we firmly believe that total elimination of the "80/20 Rule" in the short term, or even a major change in the rule, say to 50/50, would not be advisable at this time. This radical change would, in our opinion, create confusion and potential production and supply imbalances in the NRM growing countries, as well as create an unfair economic advantage benefitting one of our U.S. competitors who has a direct link to Non-Traditional NRM sources via a subsidiary operation.

PENICK CORPORATION

Aris P. Christodoulou, Ph.D.
President, C.E.O.

PENICK

CORPORATION

158 Mt. Olive Ave., Newark, New Jersey 07114 • Telephone: (201) 621-2800 • Telex: TRT 178077
FAX: (201) 821-2816 • Cable: PENICKDRUG

STATEMENT OF PENICK CORPORATION

Presented to The Sub-Committee on Crime
of the House Committee on the Judiciary

February 27, 1990

Penick Corporation is one of three U.S. manufacturers licensed to import and process Narcotic Raw Materials (NRM) derived from the Papaver Somniferum plant, into finished bulk opiate pharmaceuticals.

These bulk opiates consist of products such as Codeine Phosphate, Morphine Sulfate, Hydrocodone Bitartrate, Oxycodone Hydrochloride, etc. which we supply to both generic and brand-name pharmaceutical companies who formulate these active compounds into dosage form pharmaceutical preparations which are prescribed as analgesics, anti-tussives and for the treatment of pain.

Traditionally, the U.S. manufacturers depended on one form of NRM, i.e. Opium, that had been available mainly from India and Turkey. After Turkey ceased the production of Opium in the early seventies a world-wide shortage of NRM ensued, prompting the U.S. Government to allow U.S. manufacturers to import other forms of NRM such as Poppy Straw (PS) and Poppy Straw Concentrate (CPS). For the balance of the 1970's and until mid-1981 the U.S. manufacturers imported their

...2/4...

NRM requirements from several sources: from India in the form of Opium, from Turkey in the form of PS, and from Australia, France, Holland, Hungary, Poland and Yugoslavia in the form of CPS.

A rule published in the Federal Register on August 18, 1981 amending Section 1312.13 of Title 21, CFR directed that at least 80% of NRM imported into the U.S. shall come from India and/or Turkey -- the Traditional Sources -- and that not more than 20% originate in Australia, France, Hungary, Poland or Yugoslavia -- the Non-Traditional Sources. This rule, known as the "80/20 Rule", was designed principally to facilitate or encourage the usage of CPS from Turkey, which was at that time coming on-stream with a CPS manufacturing facility.

Penick Corporation fully supported the "80/20 Rule" as being essential at that time to help Turkey establish its position to sell CPS in the U.S. market. We have since supported Turkey in this endeavor to the best of our ability, not only by purchasing CPS from this source, but also by collaborating with Turkey in helping it produce a quality of CPS that would meet standards required under FDA regulations.

In this period of time, in addition to its sales of CPS to the U.S., Turkey made inroads in other world markets, both with its CPS as well as with its derivatives such as Codeine and Morphine. It is our

...3/4...

opinion that Turkey no longer needs commercial protection in the U.S. for its output. We also believe that Turkey's apparent success in other world markets has encouraged the irresponsible commercial behavior which we are currently experiencing with this supplier.

To illustrate this behavior, Penick officials were advised last year by representatives of The Turkish Opiates Board (TMO), that due to serious drought and a resulting poor poppy straw harvest in 1989, Turkey would likely not be able to meet its contractual commitments for CPS in 1990. TMO representatives estimated that the 1989 harvest would yield only 9,000 kgs. AMA equivalent, which is less than they normally export each year. Furthermore, we understand from INCB officials that Turkey's stockpile has been severely reduced. Penick has a contract with TMO, entered into in 1988, to purchase several tons of CPS during the balance of 1989. TMO representatives assured us, in a meeting we had with them in May 1989, that they would honor that contract. Shortly after our meeting we received their telex advising that the price of our contracted CPS would increase by between 40 and 50 percent. This is a clear breach of TMO's contractual supply obligations to Penick.

Penick Corporation believes that at this time a gradual increase in the quotas be allowed from Non-Traditional Sources. This would give the U.S. importers needed flexibility and protection against sudden

...4/4...

shifts in quantities and prices dictated by the Traditional Sources to the U.S. importers. We have stated this position on previous occasions in Washington in recent years.

We now advocate, as we have in the past, an initial change in the percentage allowed to be imported from Non-Traditional Sources from 20% to 30%. This first step should be followed by yearly reviews designed to adjust for possible supply anomalies in the producing countries. This approach of gradual change in the "80/20 Rule" would allow normal supply/demand market forces to be the key control for NRM production.

Further, we firmly believe that total elimination of the "80/20 Rule" in the short term, or even a major change in the rule, say to 50/50, would not be advisable at this time. This radical change would, in our opinion, create confusion and potential production and supply imbalances in the NRM growing countries, as well as create an unfair economic advantage benefitting one of our U.S. competitors who has a direct link to Non-Traditional NRM sources via a subsidiary operation.

We believe Penick's position, as defined above, is reasonable and realistic, in view of the current world market situation.

PENICK CORPORATION

Aris P. Christodoulou, Ph.D.
President, C.E.O.

PENICK

CORPORATION

158 Mt. Olive Ave., Newark, New Jersey 07114 • Telephone: (201) 621-2800 • Telex: TRT 178077
FAX: (201) 621-2816 • Cable: PENICKDRUG

BIOGRAPHICAL SKETCH

Aris P. Christodoulou

Aris P. Christodoulou, is President, Chief Executive Officer and Chairman of the Board of Directors of Penick Corporation. He is also President and Director of Mayfair Pharmaceutical Inc., the holding company for Penick, and a Director of Mayfair Capital Partners, Inc., an investment banking and money management firm specializing in the chemical and pharmaceutical industries, which he founded in 1980. Previously he was a First Vice President and Senior Chemical Analyst at Blyth Eastman Dillon & Co., Merrill Lynch and Lehman Brothers. Prior to his Wall Street experience, he had been a Senior Scientist with Booz, Allen & Hamilton. He is a graduate of M.I.T. and holds a M.S. and a I.E. Professional Degree from Columbia University and a Ph.D. in Chemical Engineering from City University of New York.

Mr. HUGHES. Mr. Nystrom, welcome.

STATEMENT OF LLOYD W. NYSTROM, BUSINESS DIRECTOR, MEDICINAL NARCOTICS, MALLINCKRODT, INC., SPECIALTY CHEMICALS CO., ST. LOUIS, MO

Mr. NYSTROM. Thank you very much, Mr. Chairman.

Mallinckrodt is pleased to testify on the importation of opium raw materials. We thank Chairman Hughes, the subcommittee, and the staff for their courtesy and consideration for inviting Mallinckrodt here today.

Now licit narcotic raw material import policy is a complex subject which should not be tampered with lightly. Mallinckrodt's views have been formed over a century of experience of buying and importing large quantities of licit narcotic raw materials to meet medical and scientific needs in the United States.

Mallinckrodt fully supports the recommendations of the Department of State and of the Drug Enforcement Administration as presented in their report to the Congress entitled, "Licit Opium Review." Mallinckrodt strongly supports continuation of the 80-20 rule without exception, and our reasons are as follows.

Number one, Mallinckrodt must have a reliable supply of opium from India, without which we cannot produce enough thebaine and noscapine.

Number two, India and Turkey are reliable, traditional suppliers who deserve our support.

Number three, changes in the current supply system will have profound and unanticipated consequences. For example, the decision to stop production in Turkey in the early 1970's caused a major supply disruption, the unanticipated consequences of which we are still addressing 20 years later.

Four, a shifting policy on imports would favor foreign commercial raw material producers, principally in Australia. Placing the U.S. supply of this regulated specialty in the hands of a very few foreign corporations will invite abuse and trouble.

Mr. Chairman, the U.S. narcotics policy is, first and foremost, based on control and security followed closely by sufficiency of supply. Narcotics is not a free trade commodity. We are not talking about pig iron but about highly regulated, dangerous substances which are necessarily limited as to their supply and the number of suppliers. In our view, there has already been too much loosening up on the strict control of trade in narcotics laid down in treaties, conventions, and laws since early in this century.

Why doesn't the United States grow its own poppies, even though it has the world's largest licit consumer market? The answer: In order to offer an example to the rest of the world of adherence to the spirit and the letter of these international control agreements. That is not our words; they come out of the Federal Register, page 4 of attachment 9 to our written submission.

There has been no shortage of narcotic raw materials to the United States in the past 12 years, there is no shortage now, and there is not likely to be any in the foreseeable future. All American bulk manufacturers are capable and equipped to process both

gum opium and concentrated poppy straw. The entire U.S. requirement can be supplied from gum opium.

India has a large inventory of opium in stock, and based on the content of total useful alkaloids, Indian opium is cheaper than concentrate at prices that have been charged over the past 2 years. We have documented current prices of opium and concentrated poppy straw on a chart on page 18 of our written testimony.

Now, it is sometimes said that concentrated poppy straw is safer from diversion than opium. This is simply not true. Concentrate of poppy straw is not inherently safer. It is the intensity of policing of any raw material which prevents its diversion.

Contrary to popular perception, illicit concentrate of poppy straw could be produced by peasant farmers just as crude cocaine paste is produced in South America. Cocaine paste is, in fact, a concentrate of coca leaf. Whether it is opium, concentrate or poppy straw, or cocaine, policing is the key to safety from diversion.

In our view, so long as India and Turkey remain viable, responsible suppliers, we should continue to honor our treaty obligations and the policy of supporting them as traditional suppliers. But if, for some reason, the United States cannot honor these commitments, then we should seriously consider growing opium and poppies in the United States and closing our borders.

It makes absolutely no sense to give the U.S. market to foreign farmers from industrialized nations and to exclude American farmers from the U.S. market. That is a perversion of the policy and it takes the concept of a level playing field and turns it upside down.

Thank you.

Mr. HUGHES. Thank you very much, Mr. Nystrom.

[The prepared statement of Mr. Nystrom follows. The attachments to Mr. Nystrom's statement may be found in app. 4, p. 137.]

PREPARED STATEMENT OF LLOYD W. NYSTROM, BUSINESS DIRECTOR, MEDICINAL
NARCOTICS, MALLINCKRODT, INC., SPECIALITY CHEMICAL CO., ST. LOUIS, MO

TABLE OF CONTENTS

	<u>Page</u>
Executive Summary	1-4
Opium is an Essential Raw Material for Medical and Research Purposes	5-8
The Licit Indian Opium Crop is Well-Regulated and Controlled	8-12
The 80:20 Rule Should be Retained	12-17
The Price of Concentrate of Poppy Straw Graph, Narcotic Raw Material Price Trends	17-19
Relative Diversion Potential, Concentrate of Poppy Straw Versus Opium	19-20
Australia and the 80:20 Rule	21-23
Noscapine	23-24
Turkey's Role	24-25
Domestic Cultivation of <u>Papaver Somniferum</u>	25-26
Conclusion	26-27

TESTIMONY ON THE LICIT IMPORTATION OF OPIATE
RAW MATERIALS INTO THE UNITED STATES

THE CASE FOR CONTINUITY

Mellinckrodt Specialty Chemicals Company
St. Louis, Missouri

EXECUTIVE SUMMARY

Based on over 100 years experience as a registered importer of licit narcotic raw materials, Mellinckrodt strongly supports continuation of the import policy preference for traditional suppliers, Turkey and India, in the form of the "80:20 Rule".

Opium from India is an essential raw material for medical and research purposes. Opium alone contains the full range of alkaloids critically necessary for legitimate medical needs. Concentrate of poppy straw (CPS) contains insufficient quantities of one critically necessary alkaloid, thebaine. Thebaine is required to produce the narcotic antagonists naloxone and naltrexone, irreplaceable drugs for treating narcotic overdose, narcotic addiction and for reversal of anesthesia. Thebaine is also needed to manufacture other important analgesics.

The licit Indian opium crop is well regulated and controlled. While leakage from the licit crop has been rumored, investigation with national and international drug control agencies has resulted in no documentation of any seizure of heroin of Indian opium origin outside India.

The "80:20 Rule" was enacted by the DEA as a balance of legitimate policy concerns of the United States. It supports the international objective of market stability in opium production, supports the traditional producers and assures an adequate supply of narcotic raw materials at reasonable prices. There has been no shortage of raw materials into the U.S. since the 1970's and no shortage is foreseen.

The two Australian producers, Tasmanian Alkaloids or Extal, an affiliate of Johnson & Johnson, and Glaxo, Ltd. have led a continuing effort to discredit the "80:20 Rule" on the basis of fairness, shortages, excess inventories and other allegations. In fact, Australia subsidizes the export of narcotic raw materials, providing direct economic incentive to these companies. France first initiated growing poppies in 1974, and Australia in 1977. By 1988, these two countries produced more morphine than did India. France exported 17% of its production in 1988, while Australia exported 64%.

Since early 1987, the price of Indian opium has remained relatively stable, with material readily available and costing \$143-150 per kilogram of contained useful alkaloids. During this same period, the price of Glaxo's concentrate of poppy straw has risen from \$205 per kilogram to \$285 and of French CPS from \$196 per kilogram to \$233, also on a contained total alkaloid basis.

There is a misconception regarding the safety of concentrate of poppy straw relative to opium. Concentrate of poppy straw is not inherently safer than opium. It contains from 50-90% morphine and can be directly converted into heroin. Opium contains 10% morphine, and must be purified before the morphine can be converted to heroin. The absence of diversion of CPS is due to more policing in the relatively few areas of production and not due to any inherent safety. CPS could be manufactured by relatively simple means in ordinary equipment like crude cocaine paste.

The "80:20 Rule" does not discriminate against non-traditional suppliers any more than against U.S. manufacturers. As the DEA pointed out in its proceedings, the U.S. treats non-traditional suppliers as it treats itself, by relying on traditional sources while banning domestic cultivation. Narcotics are not free-trade products. In fact, American farmers are being discriminated against. Unlike Australian and French farmers, they are not allowed access to produce for the U.S. narcotic market.

Noscapine is a non-addictive antitussive found only in Indian opium, and is an important export product for Mallinckrodt with markets in Europe, Japan and Asia.

Turkey's concentrate of poppy straw complements Indian opium in balancing alkaloid requirements. The governments of India and Turkey have made considerable progress in controlling the flow of narcotics within licit channels. There is no reason to support foreign commercial operations in opposition to these countries by changing U.S. policy.

Mallinckrodt is deeply concerned with maintaining reliable sources of supply at reasonable prices. We would be uncomfortable with having to rely on foreign commercial suppliers. If traditional suppliers were not to remain reliable and interested, Mallinckrodt would be compelled to seek to grow our own domestic Papaver somniferum. If the U.S. is to alter its policy, then Mallinckrodt strongly believes that U.S. farmers should have the opportunity to supply the U.S. narcotic industry, and that U.S. borders should be closed to importation, as is done in both Australia and France. Such action would reduce the international movement of narcotics.

TESTIMONY ON THE LICIT IMPORTATION OF OPIATE RAW
MATERIALS INTO THE UNITED STATES:

THE CASE FOR CONTINUITY

Submitted by Mallinckrodt Specialty Chemicals Company
St. Louis, Missouri

This testimony has been prepared by Mallinckrodt, a registered United States importer of narcotic raw materials for over 100 years. Mallinckrodt believes, based on a century of experience in this industry, that Indian opium should remain available to United States manufacturers of legitimate and necessary narcotic drugs. Furthermore, the company strongly supports the continuation of the import policy preference for narcotic raw materials imported from the traditional suppliers, Turkey and India, in the form of the "80:20 Rule."

OPIUM FROM INDIA SHOULD REMAIN AVAILABLE TO UNITED STATES
MANUFACTURERS TO MEET LEGITIMATE MEDICAL NEEDS

A. Opium Is An Essential Raw Material for Medical and
Research Purposes

Gum opium, unlike poppy straw and concentrate of poppy straw, contains the full range of alkaloids used to produce narcotic drugs for legitimate medical needs: morphine, codeine, thebaine,

papaverine and noscapine. ¹ Thebaine, papaverine and noscapine are absent from crude, natural concentrate due to maturation of the poppy straw and/or the concentrate extraction process. It is the constant presence of thebaine that makes gum opium an essential raw material for therapeutic and medical research purposes.

If Indian opium were unavailable, it would become impossible to meet domestic medical needs for thebaine derivatives, naloxone, naltrexone and oxycodone. As Dr. Kathleen M. Foley, Chief, Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center, states unequivocally, naloxone and naltrexone are "irreplaceable" opioid antagonists. (Attachment I.) Their unavailability would have major therapeutic consequences: deaths from drug overdoses would increase. In addition, naloxone has become the drug of choice for anesthesia reversal in approximately 25% of general anesthesia in the United States, and reverses the life-threatening effects of shock syndrome. (See Attachments I and II). Similarly, oxycodone is a "first line" drug for managing both acute and chronic mild to moderate pain. Patients who are unable to tolerate codeine can

¹ Noscapine is an unscheduled substance which is used in Europe and Japan as a strong antitussive, and an alternative to codeine. Mallinckrodt produces this derivative for export to these countries. The approximate export value of these sales is over one million dollars per year.

tolerate oxycodone. The unavailability of oxycodone would deprive these patients of relief from pain, or, in other cases, would force physicians to resort to prescribing more powerful and more addictive analgesics.

The unavailability of thebaine would have an equally damaging impact on ongoing research which, in the past ten years, "has opened new avenues for the development of analgesics with little abuse potential or other side effects." (Attachment II.) The first generation of these "superior analgesics," nalbuphine and buprenorphine, are thebaine derivatives. As thebaine research leads to a better understanding of the "molecular mechanisms of opioid dependence," Professor P.S. Portoghese of the Department of Medicinal Chemistry, University of Minnesota, predicts that other safe and effective alternative analgesics will be identified. Thebaine research thus may hold the key to both the treatment and cure of narcotic dependency. Additionally, current research into the effects of naloxone and naltrexone indicates that they may be useful in treating alcoholism and in preventing paralysis due to spinal trauma. (Attachment II.)

In short, gum opium is a uniquely important narcotic raw material because of its thebaine content. Although morphine and codeine can be extracted from poppy straw concentrate, only gum opium can meet all medical needs for thebaine derivatives. The singular importance of thebaine has previously been acknowledged

by the Drug Enforcement Administration which, in 1981, concluded that concerns about assuring the future availability of thebaine in the face of increased reliance on concentrate of poppy straw were "well-founded". 46 Fed. Reg. 41755 (Aug. 18, 1981).

Research developments since that time underscore the significance of these concerns, and the importance of assuring that adequate supplies of thabaine remain available to meet medical needs.

B. The Licit Indian Opium Crop is Well-Regulated and Controlled

India maintains an extensive system of licenses and production controls which have historically prevented diversion of the licit crop into illicit traffic. In the past two years alone, these controls have been bolstered by additional regulatory and enforcement measures.

The Indian Narcotics Commissioner supervises three regional units, each the responsibility of a District Narcotics Commissioner (DNC) who oversees production in three states. Within the three DNC supervised regions, there are twenty-seven divisions, each headed by a District Opium Officer. The total area under poppy cultivation has been reduced from 66,000 hectares in the 1977-78 season, to 22,000 hectares in 1987-88, and 15,000 hectares in the current years. (Attachment III.) Whereas a regulatory division covered around 1,500 hectares in the past, each one is now reduced to 400 to 800 hectares.

Consequently, supervision has become much more intense. Additionally, the number of special customs police, committed to suppression of illicit narcotics trafficking, have been increased.

Farmers in the three states are licensed to cultivate a designated number of hectares, and yield requirements are set per hectare to assure that licensees sell their entire crop exclusively to the Government of India. 2 Since 1978, yield requirements have been increased by 28%. (Attachment V.). Records of production and weights are maintained by the village head cultivator, who is selected based on his prior performance and integrity. His accounts are further examined by the district officers. Producers who do not achieve the requisite yields are ineligible for future licenses, unless the shortfall was attributable to a natural calamity verified by the Narcotics Commissioner. Those who embezzle opium or tender adulterated or inferior material are prosecuted and are subject to severe penalties as traffickers.

As the International Narcotics Control Board noted in its 1988 Report, page 14, India's system of control "has been functioning effectively". Over the years, leakage from the licit crop has been rumored, as reported by the National Narcotic Intelligence Consumer Committee in its April, 1988 Report, page 72. However,

2 Applicable rules, conditions and government forms are compiled as Attachment IV.

our direct inquiries confirm that neither Interpol, the Drug Enforcement Administration, the Government of India nor the United Nations Narcotics Laboratory has documented any seizure of heroin outside India of Indian opium origin. 3

There is an acknowledged transshipment problem in India associated with illicit opium from the Golden Triangle, Afghanistan and Pakistan. There is also concern that the growing heroin addict population in India may put additional pressure on that country's regulatory system. The recent enactment of the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, approved September 6, 1988 (Attachment VI), reflects India's awareness of the seriousness of these actual and potential problems, as well as its intent to strengthen enforcement. This law permits the detention of any persons engaged in or financing "illicit traffic", including illicit poppy cultivation, narcotic drug production and transshipment. It reinforces the controls implemented under the 1985 Narcotic

³ Within India, 2.8 tons of opium were reported seized in 1988, a year in which 560 tons were produced under license. It is not known whether the amounts seized were diverted from the licit crop, or illicitly cultivated.

Drugs and Psychotropic Substances Act, Section 8, which prohibits opium production and sale outside the licensed system. 4 (See Attachment VII.) Violations of these prohibitions result in mandatory jail sentences of ten to twenty years, plus substantial fines.

These enactments, as well as the tightened administrative controls, demonstrate India's sensitivity to international concerns about control. This is consistent with India's past responsiveness. For example, in the mid-'70's, when a shortage of licit opium threatened the adequacy of medical supplies of narcotic drugs, India increased the areas under cultivation. Now, in response to concerns about excess inventories, it has radically reduced cultivation. 5 Simultaneously, it has raised yield requirements to reduce the opportunity for leakage.

4 India's control system originated in 1857, and was amplified by legislation in 1878 and 1930. The 1985 enactment updated, expanded and intensified an overall scheme for the prevention and punishment of illicit drug activity.

5 This has resulted in reducing stocks held by the Government from 3,200 tons in 1982 to 2,000 in 1988.

In short, India has effectively played the dual role of assuring an adequate supply of narcotic raw material for the world's legitimate medical needs, and maintaining an effective system of control. To foreclose Indian opium imports into the United States would both jeopardize the domestic supply of essential drugs, and subject India's ability to restrict opium production to licit channels to even greater pressures. In the face of that nation's demonstrable commitment to successful production controls, its history of responsiveness to international needs and concerns, and the essentiality of opium for medical purposes, United States narcotics policy should continue to provide for the importation of Indian opium into the United States. We should not let the scourge of drug abuse lead us to reach for false solutions to the problems of escalating illicit demand and uncontrolled illicit production. Those problems may eventually plague India no less than the United States, so, for its sake and our own, we should provide further encouragement and enforcement assistance.

THE 80:20 RULE SHOULD BE RETAINED

In 1981, the Drug Enforcement Administration issued an amended rule which requires that at least 80% of the narcotic raw material imported into this country originate in Turkey and India, the two traditional producing countries. 21 C.F.R. Section 1312.13(e). The rulemaking which produced the so-called

"80:20 Rule" was a response to efforts mainly by Australia to gain a portion of the U.S. narcotic raw materials market. The resulting 80/20 percent split was a compromise between non-traditional, new supplier interests and the clear commitment contained in U.N. Resolution 471, adopted by the United Nations Commission on Narcotic Drugs (CND) in 1979. Among other provisions, this resolution called for countries which import narcotic raw materials "to support the traditional supply countries and give all practical assistance they can to avoid the proliferation of producing/manufacturing sources for export." Substantially the same language was incorporated in CND Resolution 497 a year later.

After a rulemaking hearing, DEA Administrative Law Judge Young issued a report which construed the CND resolutions to favor preferential support of Indian and Turkish exports of opium. He concluded that the proposal to allocate a larger market share to India and Turkey was "in accord" with these resolutions, and authorized by U.S. law. (DEA Docket No. 80-18, Report to the Administrator at 48 (January 16, 1981)). The 80/20 ratio was subsequently set administratively by DEA and has remained in place since.

The rationale for both the resolutions and the rule itself recognizes that India and Turkey have been responsible and reliable suppliers of narcotic raw material for decades. Further, it acknowledges that these countries have invested

heavily in production and control systems that have enabled them to meet medical needs throughout the world, while keeping the raw material out of the illicit market. As noted in the preamble to the 80:20 Rule, "Turkey in particular has taken extraordinary measures to curtail the diversion of narcotic raw materials which formerly were the principal source of the heroin in the U.S. Furthermore, Turkey continues to actively cooperate with the U.S. in suppressing the illicit narcotic traffic which transits its borders." 46 Fed. Reg. 41775. The same cooperation must also be attributed to India.

There are, of course, some valid economic, trade and foreign policy reasons not to limit United States manufacturers to narcotic raw material imports from these countries alone as Judge Young pointed out. Nevertheless, it is equally important that the United States not encourage the expansion of non-traditional production by abandoning the allocation system, or readjusting the ratio. As a major importer of opium and concentrate of poppy straw, the United States would inevitably stimulate competition among non-traditional suppliers (e.g., France, Australia and eventually others) in the marketplace to obtain a larger market share in the United States. In this context, competition, which is advantageous where price and quality of product are the sole consumer interests, works against the public interest by destabilizing supply and demand. The CND objective of a "lasting

balance between supply and demand" 6 so as to prevent diversion of licit drugs into the illicit traffic cannot be achieved if the United States gives non-traditional producing countries an incentive to expand their sales and dislocate the market.

In fact, Australia already has a domestic, economic incentive to do just that. Pursuant to the National Health Act, the Pharmaceutical Benefits Pricing Authority of that country establishes the reimbursable cost of pharmaceutical products that are purchased by persons covered by the Act, in effect, setting domestic Australian pharmaceutical prices. A higher price is allowed on products produced by companies which (1) achieve a specified ratio of exports to imports, and (2) continue to increase their exports by at least one-third over a three-year period. If a pharmaceutical company meets these criteria, as well as some research and development specifications, "it will automatically qualify for higher prices" on domestic sales under the Act. (See Attachment VIII.)

In the context of concentrate of poppy straw sales, this means that the privately held Tasmanian producers 7 of concentrate of poppy straw and its derivatives, both of which are pharmaceutical companies, will reap a double benefit if the United States

6 CND Resolution 471, paragraph 2 and CND Resolution 497, paragraph 3.

7 There are two producers in Tasmania, Tasmania Alkaloids, an affiliate of Johnson & Johnson, and Glaxo Australia Pty. Ltd.

revokes the 80:20 Rule. In addition to increasing their export sales, they will be able to charge higher prices on their domestic Australian sales of pharmaceutical products. Thus, the Tasmanian producers would be the first to profit financially from the demise of the 80:20 Rule, at the expense of both the less-developed traditional suppliers and the stability of the licit world market for narcotic raw materials. In Mallinckrodt's view, this is a high price to pay for no significant benefit to the United States, and the enhanced risk of diversion resulting from the overproduction of poppies. In our view, there is increased risk to the strict regulation of production by the further loosening of the effective, current firm structure of international production.

The existing 80:20 Rule achieves an appropriate balance of legitimate policy concerns of the United States, as articulated at length in the 1981 report of Judge Young. It adheres to the international objective of market stability in opium production, supports the traditional producers, and assures an adequate supply of necessary raw materials at reasonable prices. There is no policy justification for abandoning this rule, and every reason to retain it. To abandon the commitment to the traditional suppliers in favor of those who have recently expanded opiate production in other parts of the world would disassociate the United States from the successful control

measures of the Commission on Narcotic Drugs. At a time when this country seeks maximum cooperation in international enforcement efforts, this is the wrong message to send around the world. (See Attachment IX for a historical analysis of the "80:20 Rule").

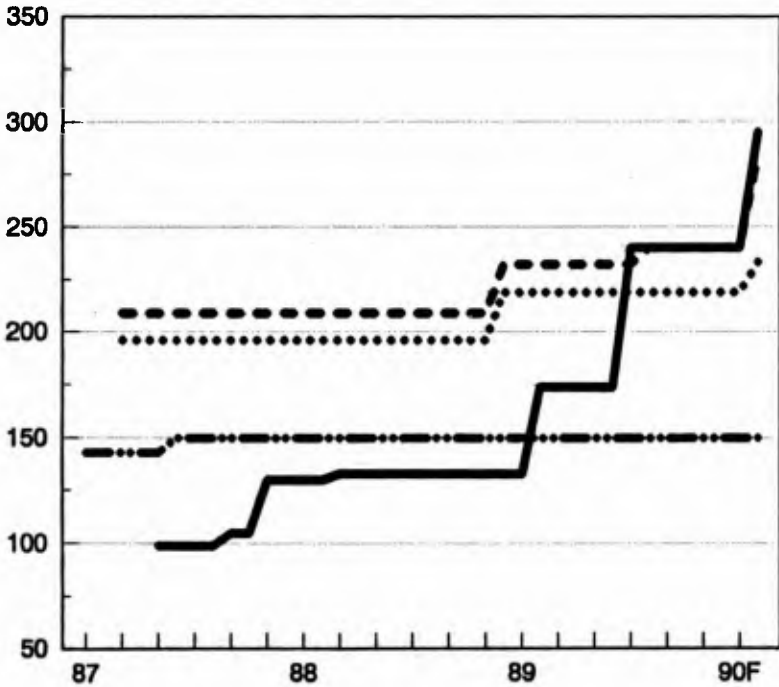
THE PRICE OF CONCENTRATE OF POPPY STRAW

Since early 1987, the price of concentrate of poppy straw quoted to as well as paid by Mallinckrodt has been regularly increasing. In contrast, the price of opium from India has remained relatively stable and low on the basis of useful alkaloid content. The following graph, page 18, clearly shows this relationship.

One of Mallinckrodt's deepest concerns regarding any change in U.S. import policy is that it would lead to greater concentration of the legally restricted raw material production capacity into the hands of foreign private firms. India and Turkey have other national investment imperatives and lack technical resources to engage in competition with large, affluent, multi-national pharmaceutical companies. Given the policy stance of the United States to deliberately forego domestic poppy cultivation and its attendant benefit to U.S. farmers in order to benefit the less developed agricultural sectors of Turkey and India, it would be egregious to transfer control of the U.S. supply to foreign private firms in developed countries.

NARCOTIC RAW MATERIAL RECENT PRICE TRENDS

\$ PER KILOGRAM ALKALOID



TMO, TURKEY	GLAXO, AUSTRALIA
SANOFI, FRANCE	OPIUM-INDIA

* includes morphine, codeine, thebaine & noscapine

There has been no shortage of raw material to U.S. bulk manufacturers. All U.S. bulk manufacturers are capable and experienced in the use of Indian opium. In addition, India holds more than a year's supply (over 2000 tons) of the world's needs for morphine as opium.

Mallinckrodt has recently been offered concentrate of poppy straw by all three of the CPS suppliers, Turkey, Glaxo (Australia) and Sanofi (France). The total quantity offered has been more than enough to meet our potential needs, but the price continues to increase and is significantly higher than the value of opium.

RELATIVE DIVERSION POTENTIAL, CONCENTRATE OF POPPY STRAW
VERSUS OPIUM

There seems to be a misconception about the safety of concentrate of poppy straw versus opium. CPS is not a "safer poppy" as it is sometimes popularly described. Both CPS and opium contain narcotic alkaloids like morphine which can be abused themselves or be converted to drugs of abuse, such as heroin. There is no additional security inherent in the CPS method. It is a perception which has been advanced mainly by those who wish a larger share of the U.S. raw material market.

The CPS processing method entails the extraction of morphine from mature poppy capsules (poppy straw) by the use of commonly

available solvents. The final commercial product is a dry powder containing 50-90% morphine which can very easily be directly converted to heroin. Opium collection entails the lancing by hand of the green capsules, the collection of the exuded latex (gum) and the subsequent drying of the product until it becomes a black, tarry material (opium) containing about 9 to 10% morphine. Diversion can be accomplished under either method of production. However, unlike concentrate of poppy straw, the morphine must be first extracted from the opium before the morphine can be converted to heroin.

CPS is not a "safer poppy". On the contrary, CPS can as easily be manufactured illicitly from mature poppies just like crude cocaine, "concentrate of coca leaf", is manufactured from coca leaves under the crudest of conditions. The level of technology required for crude CPS production is no more difficult than that required for illicit cocaine production. Heroin can be made more easily from CPS than it can be from opium since CPS has a higher morphine content.

The perception that CPS is somehow much safer in commercial, licit production because it is a modern method used in countries where it is heavily policed is erroneous. It is the policing, not the method which makes it appear to be safe from diversion.

AUSTRALIA AND THE 80:20 RULE

Multi-national pharmaceutical companies with subsidiaries in Australia have long made strong efforts to gain a larger share of the U.S. market for narcotic raw materials. Recent questions about India as a supplier of opium to the U.S. apparently have been perceived by the Australians as an opportunity to force their case for overturning the 80:20 Rule, enabling it to sell more narcotic raw material in the U.S. market and to gain resulting financial subsidies from the Australian government.

The question has been raised, whether in the terms of fairness, Australia ought to be allowed a larger share of the U.S. narcotics raw material market. Narcotics policy has always been, and should only be, based on statutory concerns for security from diversion and adequacy of supply. As such, commercial fairness, in the usual sense, is not pertinent to the determination of international or domestic narcotics policy. Consumer interests may be considered, subject, however, to the primacy of the security objective. Narcotics are not free-trade products.

If "fairness" were a valid consideration in formulating U.S. narcotics policies, it would be better applied to American farmers who have been denied the opportunity to grow narcotic raw materials in the U.S. As the DEA pointed out in the 80:20 Rule proceedings, the United States did not discriminate against other

countries in formulating its narcotics import policy, rather it treated them exactly as it treated itself, having agreed to rely on the traditional supply countries rather than develop a capacity for domestic production of raw materials. The United States agreed to and has strongly supported both the letter and the spirit of the Single Convention Treaty of 1961 which clearly places production and international trade control of narcotics outside the usual trade rules for commercial products. Clearly, strict control and conformance to successful regulatory policy, not commercial fairness, must rule when dangerous and addictive substances are at stake.

With respect to American farmers, in the 1970's U.S. companies DuPont, Merck, Mallinckrodt and Penick separately engaged in an extraordinary effort to develop the agricultural and industrial technology to produce narcotic raw materials from Papaver bracteatum, another species of poppy which contains no opium or morphine. All the companies planned to cultivate this poppy in the U.S. and had extensive experimental plots on farms in several states including North Carolina, Nebraska, Washington, Oregon, Montana and California. Despite the best efforts of the interested American companies, the support of the DEA, and a favorable ruling by ALJ Francis Young, the petition to allow production in the U.S. was denied by the U.S. government due to perceived adverse foreign policy considerations. Australia, along with other Commonwealth countries, was in the forefront of the foreign governments which strenuously objected to the plans

for domestic cultivation. Stern diplomatic initiatives against the notion of the U.S. "growing their own" came from many quarters. The end result, which prohibited domestic cultivation of the morphine-free poppy, plainly demonstrated that "fairness" to American farmers and industry was not a consideration in the policy decision.

Even if fairness were a compelling consideration however, Australia's position would not be enhanced. Both of the companies there started producing narcotic raw materials in Tasmania as an internal supply source. They now seek to expand this business to gain special financial rewards offered by the Australian government in order to further develop the Australian pharmaceutical industry. Under these circumstances, where foreign companies seek to promote an unneeded and very likely damaging decision in the U.S., for their private, financial gain, the concept of "fairness" seems particularly inapt. It would be a perversion of U.S. narcotic raw material policy to act contrary to the interests of India and Turkey preferred suppliers of long and honorable standing while rewarding private concerns in Australia.

NOSCAPINE

Noscapine can only be obtained from Indian opium in commercial quantities. Mallinckrodt exports its production predominantly to Japan and Europe where it is used extensively as an anti-tussive.

It is not used in the U.S. where clinical trials would be required in order to be approved by the Food and Drug Administration (FDA). Since noscapine can not be patented or otherwise protected, U.S. pharmaceutical companies do not wish to invest the considerable sum required to obtain FDA approval for its use.

Some months ago, it was rumored that noscapine might have side effects. It was determined that this perception was based on the re-issue of an outdated report, and U.S. toxicologists reviewed and sharply discounted the rumor. There has been no concern shown by Japanese or European health authorities.

TURKEY'S ROLE

Mallinckrodt supports Turkey's U.S. market position under the 80:20 Rule as strongly as we do that of India's. Turkey's concentrate of poppy straw complements gum opium to balance alkaloid requirements. Mallinckrodt's policy position has always been one of balancing the necessity for strict control of production and distribution under conditions that maintain a continuous and uninterrupted supply. This requires reliable, long term sources of supply. The governments of Turkey and India have performed that role well and wish to continue it for social as well as economic reasons. Unlike the purely industrial company producers, farmers located in Turkey and India grow poppies for uses other than solely the narcotic content. In

fact, Turkey and India could easily supply the world's needs for licit narcotics at reasonable prices as a by-product if they were allowed to do so. Turkey's large investment in the Bolvadin extraction plant is currently under-utilized, and it would be a shame if it were to stand completely idle. Turkey has had and is having considerable difficulty sustaining the burden of their large investment in raw material production. Turkey should be aided by continuing current U.S. policy, with support of the 80:20 Rule. There is no reason to support multi-national pharmaceutical companies which are in competition with Turkey by changing or making exceptions to current U.S. policy.

DOMESTIC CULTIVATION OF PAPAYER SOMNIFERUM

Mallinckrodt is deeply concerned that changes or exceptions to U.S. import policy will jeopardize the continued reliability of India and Turkey as suppliers and result in disruption and uncertainty. As a major supplier of narcotics to the U.S. medical and scientific community, Mallinckrodt is obliged to seek long term, reliable sources of supply at reasonable prices. We are not comfortable with the prospect of having to rely more and more on foreign, commercial suppliers without the freedom to choose to grow our own in the United States. Mallinckrodt has never supported the proliferation of sources of supply, relying on the integrity of the governments of India and Turkey to deliver adequate supplies at reasonable prices.

It is our position that should current U.S. policy be changed, the objective or result of which is likely to cause less support for the current suppliers, we would be compelled to seek domestic production. U.S. agricultural technology and land resources are fully able to commercially grow poppies, and U.S. industry is capable of processing them. If foreign commercial suppliers are to be granted greater access to the U.S. market, then U.S. farmers should have the opportunity to supply the U.S. narcotic industry. The U.S. borders to narcotics could then be closed. It should be noted that both France and Australia close their own borders to raw material and finished goods importation while fostering exports.

CONCLUSION

There is no domestic nor international rationale favorable to the U.S. to support a change in U.S. policy. There has been no shortage of narcotic raw materials. Both Turkey and India have been responsible suppliers. Both have invested in diversion control measures and both have peasant farmer populations with a long history of growing poppies for other than medicinal needs. Changing the successful current policy with no apparent valid reasons other than to benefit Australia, France and perhaps other industrialized nations, to the exclusion of the traditional suppliers and without benefit to the U.S., would be ill-founded and risky.

U.S. actions taken in the early 1970's, aimed at altering the narcotic raw material supply system, have caused many of the current narcotic import issues with which we are now confronted the over-supply of poppy production, the over-investment by new producers which now clamor for more U.S. market share, high prices to consumers followed by very low prices, and large stockpiles of crudes are all direct results of the change in U.S. raw material policy almost twenty years ago. U.S. policy should have a long term focus with the primary objective of providing a stable, continuous supply of raw materials.

As to domestic Indian diversion and the movement of illicit drugs through India, the U.S. should support Indian government efforts to attack these problems directly to bring them under control. Mallinckrodt does not believe that objective will be furthered by diminishing India's U.S. market or by strengthening India's commercial rivals. Changing or making exceptions to the current U.S. import policy to favor Australia and France will lead toward destabilizing the raw material supply system and will likely result in more surplus narcotic raw material production as the unchecked suppliers grow more poppies for "their larger share" of the U.S. market.

Mr. HUGHES. Let me just ask you first, what is the mix of concentrated poppy straw and opium gum that is imported by your company?

Mr. NYSTROM. Well, it varies from year to year, depending on the relative prices. A couple of years ago, in 1987-88, we took the lead in importing quite a lot of concentrated poppy straw from Turkey and sort of broke the logjam in reducing their inventory at that time, their stockpile, and we took about 13,000 kilos in each of those 2 years. We have throttled back since the price has come up and have been using less. This past year, we imported 6,000 or 8,000 kilos of AMA in concentrate, but we plan to import a lot less this year because the price simply doesn't justify it.

Mr. HUGHES. So this past year, what was the ratio of concentrated poppy straw to opium gum?

Mr. NYSTROM. Let's see. We had about 125 tons of opium and about 8,000 kilos of AMA; 10 percent times 125; I have to figure that out, but it is roughly 30 percent or something like that.

Mr. HUGHES. Is concentrated poppy straw.

Mr. NYSTROM. Yes.

Mr. HUGHES. And 80 percent, roughly, is opium gum.

Mr. NYSTROM. Yes.

Mr. HUGHES. I see.

Is that because of price, or is that because of some of the other substances you extract from the opium gum?

Mr. NYSTROM. We import a great deal of opium gum and rely on it a great deal because we need a lot of thebaine, and we also have good markets for our noscapine.

Mr. HUGHES. Noscapine also?

Mr. NYSTROM. Noscapine as well, yes.

Mr. HUGHES. OK.

Do you import any of your supply of concentrated poppy straw from any nontraditional countries?

Mr. NYSTROM. Yes. We normally follow the practice of dealing with all of the suppliers of the world, and so we have imported from France, from Australia, from Turkey of course, and the gum opium from India.

Mr. HUGHES. Am I to take it that you would prefer to deal with the countries as opposed to dealing with some of the firms that process it? Am I reading your testimony correctly?

Mr. NYSTROM. We don't have any problem under the current situation with the 80-20 rule. Our problem and our concern is that in the future, should it shift over to be dominated by private companies, I think we would be in a very difficult position.

Mr. HUGHES. So you prefer to deal with the countries of source as opposed to companies that are processing.

Mr. NYSTROM. We have relied on the countries, traditional countries, for over 100 years, and we have never been unhappy with price or availability.

Mr. HUGHES. I see.

Mr. Stratmeyer, you indicated that you would like to see a change in 80-20. What formula did you have in mind?

Mr. STRATMEYER. The change we would recommend is that we could buy as much or little opium as we wanted; opium would be taken out of the 80-20 rule.

Mr. HUGHES. Altogether?

Mr. STRATMEYER. Altogether.

Mr. HUGHES. I thought I understood you to say you wanted to change the formula with regard to traditional and nontraditional supplies, the so-called 80-20 rule, as far as the concentrated poppy straw. Did I misunderstand you?

Mr. STRATMEYER. No. We would find it quite acceptable to guarantee Turkey some percent of our CPS purchases.

Mr. HUGHES. What percent did you have in mind?

Mr. STRATMEYER. Well, we have mentioned 50 percent to Turkey.

Mr. HUGHES. How about you, Dr. Christodoulou?

Dr. CHRISTODOULOU. We have, as recently as 1986, and earlier, back in 1984, processed, almost 100 percent, if not 100 percent, of our requirements using opium. In the other intervening years, we had been using both CPS and opium, and it was really a market judgment as to what was of value and what were the byproduct requirements at the time. Obviously, we would like the flexibility and the facility to continue to do so.

In the past couple of years, we have been using a larger percentage of CPS in the total mix, and currently, I believe, we are more balanced on a 50-50 kind of a basis before the Turkish problem that I mentioned occurred.

Mr. HUGHES. I take it from your testimony that the supply was there, it is just that the price was going to be a lot different than you had bargained for.

Dr. CHRISTODOULOU. That is right. As I phrased it, it was a contract breach on price. However, there was no clear commitment that the supply would be there for Penick in 1989, and serious questions exist as to the availability for 1990..

We make estimates of our raw material requirements and project forward based on our contracted-for raw materials, and then make commitments to our customers, the U.S. drug industry, based on an assumption of a reliable supply.

Mr. HUGHES. Who sets that price? Is it the Board, Turkey?

Dr. CHRISTODOULOU. The market sets the price. Oh, you are talking in Turkey. Yes, the Turkish price is set by the Board, the TMO.

Mr. HUGHES. The TMO determines price based upon supply or what?

Dr. CHRISTODOULOU. How would you answer, Joe? You have known TMO for more years than I.

Mr. HUGHES. What is the criterion they use to set the price?

Mr. BAORTO. TMO bases their price on market conditions. In the past, what TMO has done, they have had a stockpile of CPS which had been accumulating for a number of years, and they aggressively went out in the market and contracted at very competitive prices to sell their stockpile, which, of course, they have successfully done.

I think what we are seeing now is that those commitments that they have made out in the world market—and this, I must say, is not only a situation which involved only Penick, but we know for a fact that also other non-U.S. buyers of CPS have faced the same situation, where TMO has reneged or is trying to renege on commitments that they have made on contracts they had made back in 1988. They have simply reneged on price for 1989, not on quanti-

ties, and therefore not a case of "force majeure," but they have also indicated to us severe shortages which could lead to lack of supply to us in 1990. They have said, "Well, we have this material available for 1989, but you have to pay x price."

Mr. HUGHES. What do you think has happened? You have worked in this business for 25 years, so you basically have seen it, over the years, change, evolve, into the present system. What has happened to the supply that would enable them to basically dictate the kind of price you are talking about? What has caused the distortions, dislocations, and problems you are now experiencing?

Mr. BAORTO. I think what we see in Turkey particularly, and this is our concern, is that there is a lack of understanding of the market conditions and of managing the sale and the pricing of what they can produce, and perhaps a lack of understanding of their production capabilities.

Mr. HUGHES. Is it monopoly pricing at this point? Is it because of the concentrated power that their assured supply of the market gives them that they are able to basically renege on contracts?

Mr. BAORTO. Absolutely. We see it that way, yes.

Mr. HUGHES. The gentleman from Florida.

Mr. McCOLLUM. Thank you.

Mr. Nystrom, I find it interesting in your testimony and in some of the written materials you have provided to us that the conclusion is drawn that heroin can be as easily or more easily produced from the straw than it can be from the opium, and that seems to be absolutely contrary to what the testimony of Mr. Haislip of DEA said, because we have his written testimony saying, "We suggest the Indian Government consider shifting from the production of gum opium to the production of concentrated poppy straw in order to eliminate itself as a source for heroin production." How do you explain this differing opinion here with DEA?

Mr. NYSTROM. He is talking about control at the field level, and that is certainly a point that he can make with authority. What we are talking about is that the concentrated poppy straw, particularly the 80-percent morphine material, that is typically imported into the United States is a very dangerous substance. It can be directly acetylated to heroin in a bathtub somewhere if it were hijacked or stolen.

Even at the field level, as I make note of in my testimony both written and oral, if the dry capsules themselves were diverted at the field level—and that is not difficult, particularly if you are in a country where it is not kept under very close control all the time—they could be milled and a concentrated poppy straw could be manufactured by a peasant farmer, just as concentrated coca leaf is done in South America.

So the point we are trying to make is that it seems with repetition the idea that concentrated poppy straw is somehow magically and inherently immune to diversion has gained acceptance. The fact of the matter is that it is a matter of better policing and better law enforcement that really prevents all kinds of diversion of any kind of raw material containing narcotics.

Mr. McCOLLUM. But you still prefer the poppy straw for your purposes to the opium.

Mr. NYSTROM. No, we don't. I don't know where that came from. We don't prefer poppy straw for our purposes at all. As a matter of fact, we normally blend concentrated poppy straw with opium in our manufacturing operation and find that to be the most practical way to use it in many instances.

Mr. McCOLLUM. What do you do with the waste products that I understand others say that they don't have any use for?

Mr. NYSTROM. Well, you are not talking about a lot of waste when you are talking about 125 tons of opium or 180 tons of opium in comparison to other industries. We use the St. Louis sewer district and have never had any problem whatsoever with sending away the waste materials from opium processing. We have been doing it there for about 100 years, and we have yet to hear a complaint about it.

Mr. McCOLLUM. Do you have any opinion on why your competitors here today say that they don't like the opium gum as far as, it is not something they want to use?

Mr. NYSTROM. Well, they have their own business reasons, I imagine, for preferring one raw material over the other. I don't think that they have particularly preferred concentrated poppy straw in the past. They have used opium. You know, they have been larger importers of opium than we have in some years. So it is maybe recently changed business conditions or their perception of how they should approach the market, et cetera, that might have changed. Our perception at Mallinckrodt is that we are a full service manufacturer of all narcotic medicines that are required in the United States for medical and scientific requirements. We feel that is the basis for our registration as a bulk manufacturer, and we pursue it with great vigor.

Mr. McCOLLUM. Mr. Christodoulou, do you want to comment on that?

Dr. CHRISTODOULOU. Yes, Mr. McCollum. If I left you with the impression that I was reinforcing the suggestion of my esteemed colleague from J&J that we are in favor of getting opium out of the 80-20 rule, that is not so. We have a wish to have both of the materials within the 80-20 rule. We are trying to make the case that we believe that the rule should be adjusted moderately in the direction that we suggested, 70-30, but including opium.

We believe that the suggestion that was made earlier of possibly taking opium outside of the 80-20 rule would represent a radical change, and I am not sure whether it would be bad or good, frankly. It would be a new definition.

Mr. McCOLLUM. Regardless of your position on the 80-20 rule, do you have a distinct preference in your manufacturing process for the straw? In other words, should we be encouraging India to go to straw and keeping the 80-20 rule in place even, or something similar to it?

Dr. CHRISTODOULOU. We have at times a need for the byproducts, the coproducts that one makes from opium. So we have a need for opium that way. We also have a need for opium should the price of opium represent better value in terms of its underlying morphine content than the morphine content available from CPS; as Mr. Nystrom indicated, in the past several years, opium has been quite

competitive in terms of morphine content, assuming you can sell all the byproducts.

My earlier point is that, really, what happened in 1989 which upset us was that there was a contract breach, number one.

Mr. McCOLLUM. I understand that.

Dr. CHRISTODOULOU. Number two, it occurred with no warning at all, which necessitated a major repositioning by us at substantial cost, and represented a detriment to the way we run our business, which we had no control over.

Mr. McCOLLUM. Mr. Stratmeyer, what are the advantages of the straw, the CPS, other than simply the question of diversion in the fields? You seem to be the strongest advocate for straw.

Mr. STRATMEYER. Well, CPS is definitely easier to process in a plant. It goes through quicker, there is less manpower needed, the work-in-process inventory is less, it is much purer product going into the system. You use less solvents, less things that do damage to the environment. These are not enormous products, but these are significant volumes in the way the environmental issues are going today.

Mr. McCOLLUM. Why would your competitors, both of whom have testified today that they use opium considerably, one of them maybe more than the other, but they both said that, why would they find that that is more useful and you find it less? I mean I don't understand. All of you are businessmen refining a similar product and obviously making competitive products. What is your rationale? How do you explain that to me?

Mr. STRATMEYER. We do, of course, process opium, and this year, of course, because of the 80-20 rule, we will be buying very significant quantities of opium, because Turkish material is not available. Also, as was pointed out, if the price of opium is attractive, since we are in a very competitive market, we certainly would purchase opium.

Mr. McCOLLUM. Other than the diversion argument and the concern that we have for that—we have heard the testimony of DEA to the effect that we can produce this all in the United States—what would be the problem if we just ended the ban on producing it here and quit worrying about our effects over in Turkey and India and just said, "To heck with you all?"

Mr. STRATMEYER. I think the problems are many, of course. First of all, you are proliferating supply sources—you know, you are adding another supply source—which is going to further complicate things. I think it would have a severe impact on Turkey, who is certainly an ally and a friend, by taking away their market.

Right now, you have the diversion that can occur from a raw material arriving at a plant, the plant producing it and supplying it to drug stores and customers. If you permit cultivation, you add a whole additional area of possible areas where there could be diversion.

Mr. McCOLLUM. Suppose we pass some rule that said that certain farmers designated could grow this just for your three corporations and you couldn't buy it anywhere else but you could buy it just from them? How would something like that work right here in the United States? Wouldn't that be a pretty cheap source for you probably?

Mr. STRATMEYER. What the economics would be I really don't know. It could be cheap; it could be expensive.

Mr. MCCOLLUM. What do you think about that, Dr. Christodoulou?

Dr. CHRISTODOULOU. We have been happy over the years—not happy; let me rephrase that. We have learned to live with the 80-20 rule. We believe that the new issue that you bring up of possible growth or cultivation of this material in the United States would open up new issues for us. We are the smallest of the three manufacturers in total corporate size, but we have a major market share. We have a share which is quite similar to the other two companies. If there is any integration threat—in other words, if we have to actually go out and invest in farms and the necessary infrastructure in order to guarantee that we have access to these farmers that you mentioned and to these plots—that would obviously be something that we would have to take into consideration.

If you are suggesting that these are neutral farmers that would be available to all three on a pro rata basis or on some fair basis—

Mr. MCCOLLUM. Yes, that would be more likely. I wasn't thinking of any exclusivity.

Dr. CHRISTODOULOU. I repeat, it is something we could learn to live with, as we learned to live with the 80-20 rule. There may be advantages; there may be disadvantages. We would obviously have to study it.

Mr. MCCOLLUM. I understand. You are not ready to make a full commitment on it.

Dr. CHRISTODOULOU. I am not ready to make a negative statement on it, is really what I am telling you.

Mr. MCCOLLUM. All right. And then Mr. Nystrom, and then I am going to quit here. I have run out my string here, but I want to give you a chance to respond to that suggestion of U.S. production. Would you find a problem with U.S. production as far as sources for you if we went away from these foreign sources?

Mr. NYSTROM. This hits me right in the area on which I am probably more expert than on anything else, and that is agricultural development. Aside from that, I think I echo Mr. Christodoulou's comments in that the 80-20 rule is the proper way to proceed, and that is exactly what we recommend and stand for and support fully.

What we are saying is that if we are going to somehow change it and destroy the 80-20 rule, go away from the rules entirely that have been formulated over all these years and go in a different direction, then very seriously ought to be considered the possibility of growing our own in the United States. That is certainly a distinct possibility. I wouldn't think the economics would be any different from growing them in France or growing them in Tasmania as is currently the case. What they can do there I am sure we can do equally as well and probably with the same set of economics. I would think maybe there is less competition for land, and good land, irrigated land, in our western areas compared to France and Tasmania that would accommodate a poppy crop extremely well.

So I don't have any concern or problem with advocating going in that direction, assuming that there is going to be some great

change in the way that we manage our imports of narcotic raw materials from the present scheme.

Mr. McCOLLUM. Thank you very much.

Thank you, Mr. Chairman.

Mr. HUGHES. I just have a couple more questions.

Is there a market for noscapine today?

Mr. NYSTROM. Yes, there is. It is a very good market.

Mr. HUGHES. Is there a good market?

Mr. NYSTROM. Yes.

Mr. HUGHES. How about for thebaine?

Mr. NYSTROM. We use all the thebaine that we can manufacture, and, as a matter of fact, we buy from our fellow bulk manufacturers in the United States when they have any available.

Mr. HUGHES. Is it fair to assume that that is why you want to keep your options open with regard to opium gum?

Mr. NYSTROM. It is one of the reasons, yes.

Mr. HUGHES. In addition to the fact that it provides some flexibility.

Mr. NYSTROM. Yes.

Mr. HUGHES. You use it, I gather, to blend with the concentrated poppy straw.

Mr. NYSTROM. Yes. I made that point because I heard Mr. Stratmeyer mention that they are not fungible, and that is really not the case, I don't think, as far as we are concerned, at least. We find when we have both of them we blend, and there are other times when we don't, et cetera. So we are completely flexible in our manufacturing operation.

Mr. HUGHES. How about Penick? Do they blend concentrated poppy straw and opium gum?

Mr. BAORTO. Yes. I think that, of course, they are not fungible in the sense that when one company plans to process more opium than poppy straw it will require more manpower and will require a longer lead time to prepare for processing opium as opposed to concentrate.

Mr. HUGHES. Is your processing different than Mallinckrodt's?

Mr. BAORTO. I don't know what Mallinckrodt's processing system is.

Mr. HUGHES. What does your intelligence tell you?

Mr. BAORTO. But my intelligence, or my knowledge, tells me that to handle opium and to process opium requires more manpower. That is a longer operation; it takes more steps. You have several more steps before you reach the same point where you will be loading concentrate, and it is as simple as that.

Mr. HUGHES. It is interesting. We have three different manufacturers with three different approaches to how to deal with the problem. Mallinckrodt likes the 80-20 rule and wouldn't change anything about it. As I understand it, Penick would change it but would retain some percentage, maybe reduce the percentage that is allocated to the traditional suppliers, Turkey and India, but would certainly not eliminate opium gum from the purview of the rule. Johnson & Johnson, by the same token, would basically maintain some percentage; they would reduce it perhaps to 50-50, 50 to traditional, 50 percent nontraditional, but they would eliminate opium gum, as I understand it, from the purview of the rule.

Dr. CHRISTODOULOU. Mr. Chairman.

Mr. HUGHES. I can see that you have the same problem getting a consensus as we do.

Dr. CHRISTODOULOU. I would just like to make a small change to your perception of Penick's position. We are strongly of the opinion that a first step be made in changing the 80-20 rule. What the consequence of that step is we are prepared to take in the marketplace. In other words, if that consequence is eventual elimination of the 80-20 rule, as long as it takes a 5-year time period rather than being done immediately in one step, we are willing to abide by and live under that kind of condition.

Mr. HUGHES. I suspect—and I am sure Mr. Nystrom will correct me if I am wrong—that one of the concerns that Mallinckrodt has is that we may end up with Johnson & Johnsons controlling the supply of concentrated poppy straw. What do you have to say about that?

Mr. STRATMEYER. There are a number of things I can say about that. First of all, the growing area in Tasmania is definitely limited. It is not a big island. You cannot grow anything in the western portion. Right about now, we feel that ourselves plus Glaxo, which both grow there, have reached pretty close to capacity with current crops being what they are. In other words, we are competing with peas, we are competing with pyrethrum flowers, and so on and so forth. So our ability to expand is very limited.

We do sell these products around the world to many other companies, and we think that is very good because we don't want to have a single complex that is entirely dependent on the U.S. codeine market; we would rather have diversity.

Mr. HUGHES. I have seen some figures that suggest that Australia could increase their capacity by as much as 20 percent.

Mr. STRATMEYER. I think 20 percent is the maximum, and that would include developing better poppies. We have already made a lot of progress here. It would require an even better poppy and maybe some better yields. But I think—and I speak only for Tasmanian alkaloid—the 20 percent is an out limit; Glaxo may have a different opinion. There are laws in Australia for intracompany transfers. The United States has these also. We cannot transfer CPS to the United States at a price different than the current selling price to other parts of the world. Otherwise, we would be depriving Australia of taxes, because we would be cutting our profits in Australia.

I should say that in the years we have been in the business we have never purchased CPS cheaper from Tasmanian alkaloid than the world price for either opium or CPS from Turkey, or France, and other countries; that has never happened.

I would also like to mention that since we entered the codeine business in the States about 10 years ago, the price of codeine has dropped by 60 percent. We have increased competition. That means what cost \$100 10 years ago is costing \$40 today.

Since we started selling bulk codeine phosphate, the selling prices of the three companies in this market has dropped by \$10 million a year. So we have definitely benefited the consumer by the way we have moved into the marketplace.

We acquired Tasmanian alkaloid initially because we wanted an assurance that we would always have supply. I lived through the shortage of the midseventies, and I feel that if it weren't for the current Indian excess inventory there is always the possibility of shortage when you are dealing with countries that don't run their production as a business.

So these are the reasons I feel that we are really not a threat in that area.

Mr. HUGHES. How much codeine can be extracted from concentrated poppy straw?

Mr. STRATMEYER. Well, actually, you extract the morphine, and then you methylate the morphine, and for codeine phosphate you end up with anywhere from 1.2 to 1.35 kilograms of codeine phosphate per kilogram of morphine as you purchase it.

Mr. HUGHES. So a very small part.

Mr. STRATMEYER. You pay for the concentrate by AMA content—that is, anhydrous morphine alkaloid. You buy maybe 100 kilograms of anhydrous morphine alkaloid, and from that you will get maybe 120 to 135 kilograms of codeine phosphate.

Mr. HUGHES. I understand that the controls in Australia are very secure, that they have done a very good job of controlling the growing areas and transportation.

Mr. STRATMEYER. We think so.

Mr. HUGHES. And that the instances of diversion, they do occur, but they don't occur very often.

Mr. STRATMEYER. Very, very seldom, and very minor when they do occur.

Mr. HUGHES. All right. Well, thank you very much. You have been very helpful to us today. It has been a very good hearing, and we appreciate your contributions. It is an important issue, and we are going to continue to take a look at it. Thank you very much.

That concludes the testimony for today. The subcommittee stands adjourned.

[Whereupon, at 12:32 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDICES

APPENDIX 1.—PUBLIC LAW NO. 100-690, NOVEMBER 18, 1988, SECTION 4307: UNITED STATES RELIANCE ON LICIT OPIUM GUM FROM FOREIGN SOURCES

102 STAT. 4274

PUBLIC LAW 100-690—NOV. 18, 1988

SEC. 4307. UNITED STATES RELIANCE ON LICIT OPIUM GUM FROM FOREIGN SOURCES.

President of U.S.

(a) **REVIEW REQUIRED.**—The President shall conduct a review of United States narcotics raw material policy to determine—

(1) the current and reserve international needs for opium-derived pharmaceutical and chemical products, and the relative capabilities for meeting those needs through the opium gum process and the concentrated poppy straw method of production;

(2) whether the United States should continue to rely on a single foreign country for all its licit opium gum;

(3) whether it should be United States policy to encourage all countries which produce licit opium to use the concentrated poppy straw method of production; and

(4) what options are available, consistent with treaties to which the United States is a party, to reduce United States reliance on licit opium gum from foreign sources.

(b) **REPORT TO CONGRESS.**—The results of this review shall be reported to the Congress not later than 6 months after the date of enactment of this Act.

SEC. 4308. AFGHANISTAN AS A HEROIN SOURCE.

(a) **FINDING.**—The Congress finds that Afghanistan remains the source of most of the heroin exported from southwest Asia.

(b) **STATEMENT OF POLICY.**—It is the sense of the Congress that—

(1) the United States Government should pursue efforts to press the Government of Afghanistan, and should work with the Mujahadeen—

(A) to reduce production and trafficking in areas under their respective control, and

(B) to encourage drug eradication, interdiction, and crop substitution in Afghanistan; and

(2) an initiative should be developed which could be put in place as the Mujahadeen and successors to the present Kabul regime begin to exert more civil authority.

APPENDIX 2.—DEA ISSUANCE OF IMPORT PERMIT, 21 CFR 1312.13

Drug Enforcement Administration, Justice

§ 1312.13

136 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 36 FR 26609, Sept. 24, 1973, and amended at 39 FR 43218, Dec. 11, 1974; 45 FR 74715, Nov. 12, 1980; 51 FR 5319 and 5320, Feb. 13, 1986; 52 FR 17289, May 7, 1987]

§ 1312.13 Issuance of import permit.

(a) The Administrator may authorize importation of any controlled substance listed in Schedule I or II or any narcotic drug listed in Schedule III, IV, or V if he finds:

(1) That the substance is crude opium, poppy straw, concentrate of poppy straw, or coca leaves, in such quantity as the Administrator finds necessary to provide for medical, scientific, or other legitimate purposes;

(2) That the substance is necessary to provide for medical and scientific needs or other legitimate needs of the United States during an emergency where domestic supplies of such substance or drug are found to be inadequate, or in any case in which the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Controlled Substances Act (21 U.S.C. 823); or

(3) That the domestic supply of any controlled substance is inadequate for scientific studies, and that the importation of that substance for scientific purposes is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(4) That the importation of the controlled substance is for ballistics or other analytical or scientific purposes, and that the importation of that substance is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(b) The Administrator may require that such non-narcotic controlled substances in Schedule III as he shall designate by regulation in § 1312.30 of this part be imported only pursuant to

the issuance of an import permit. The Administrator may authorize the importation of such substances if he finds that the substance is being imported for medical, scientific or other legitimate uses.

(c) If a non-narcotic substance listed in Schedule IV or V is also listed in Schedule I or II of the Convention on Psychotropic Substances, 1971, it shall be imported only pursuant to the issuance of an import permit. The Administrator may authorize the importation of such substances if it is found that the substance is being imported for medical, scientific or other legitimate uses.

(d) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(e) Each import permit shall be issued in sextuplet and serially numbered, with all six copies bearing the same serial number and being designated "original" (Copy 1), "duplicate" (Copy 2), etc., respectively. All copies of import permits shall bear the signature of the Director or his delegate, and facsimiles of signatures shall not be used. No permit shall be altered or changed by any person after being signed by the Administrator or his delegate and any change or alteration upon the face of any permit after it shall have been signed by the Administrator or his delegate shall render it void and of no effect. Permits are not transferable. Each copy of the permit shall have printed or stamped thereon the disposition to be made thereof. Each permit shall be dated and shall certify that the importer named therein is thereby permitted as a registrant under the Act, to import, through the port named, one shipment of not to exceed the specified quantity of the named controlled substances, ship-

§ 1312.14

ment to be made before a specified date. Not more than one shipment shall be made on a single import permit. The permit shall state that the Administrator is satisfied that the consignment proposed to be imported is required for legitimate purposes.

(f) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the Administrator shall permit, pursuant to 21 U.S.C. 952(a)(1) or (a)(2)(A), the importation of approved narcotic raw material (opium, poppy straw and concentrate of poppy straw) having as its source:

- (1) Turkey,
- (2) India,
- (3) Yugoslavia,
- (4) France,
- (5) Poland,
- (6) Hungary, and
- (7) Australia.

(g) At least eighty (80) percent of the narcotic raw material imported into the United States shall have as its original source Turkey and India. Except under conditions of insufficient supplies of narcotic raw materials, not more than twenty (20) percent of the narcotic raw material imported into the United States annually shall have as its source Yugoslavia, France, Poland, Hungary and Australia.

[36 FR 23624, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 48 FR 41776, Aug. 18, 1983; 52 FR 17289, May 7, 1987]

§ 1312.14 Distribution of copies of import permit.

Copies of the import permit shall be distributed and serve purposes as follows:

(a) The original and quintuplet copies (Copy 1 and Copy 5) shall be transmitted by the Administration to the importer, who shall retain the quintuplet copy (Copy 5) on file as his record of authority for the importation, and shall transmit the original copy (Copy 1) to the foreign exporter. The foreign exporter will submit the original copy (Copy 1) to the proper governmental authority in the exporting country, if required, as a prerequisite to the issuance of an export authorization. This copy of the permit will accompany the shipment. Upon

21 CFR Ch. II (4-1-89 Edition)

arrival of the imported merchandise, the District Director of the U.S. Customs Service at the port of entry will, after appraising the merchandise, forward the original copy (Copy 1) to the Drug Control Section with a report on the reverse side of such copy, showing the name of the port of importation, date prepared, name and net quantity of each substance, and report of analysis of the merchandise entered.

(b) The duplicate copy (Copy 2) shall be forwarded by the Administration to the proper governmental authorities of the exporting country.

(c) The quadruplet copy (Copy 4) shall be forwarded by the Administration to the District Director of the U.S. Customs Service at the U.S. port of entry, which shall be the customs port of destination in the case of shipments transported under immediate transportation entries, in order that the District Director may compare it with the original copy (Copy 1) and the bill of lading upon arrival of the merchandise. If a discrepancy is noted between corresponding items upon different copies of a permit bearing the same serial number when compared by the District Director, he shall refuse to permit entry of the merchandise until the facts are communicated to the Administration and further instructions are received.

(d) The triplicate copy (Copy 3) and sextuplet copy (Copy 6) shall be retained by the Administration.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26809, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988]

§ 1312.15 Shipments in greater or less amount than authorized.

(a) If the shipment made under an import permit is greater than the maximum amount authorized to be imported under the permit, as determined at the weighing by the District Director of the U.S. Customs Service, such difference shall be seized subject to forfeiture, pending an explanation; except that shipments of substances exceeding the maximum authorized amount by less than 1 percent may be released to the importer upon the

APPENDIX 3.—A REPORT SUBMITTED BY RAYMOND J. STRATMEYER, ENTITLED, "ECONOMIC ANALYSIS OF U.S. NARCOTIC MATERIAL POLICY," MARCH 1989, BY JANUSZ A. ORDOVER AND CARL SHAPIRO

This report has been prepared on behalf of the Johnson and Johnson Corporation to provide information to the U.S. State Department, the Drug Enforcement Administration and the Food and Drug Administration as part of their review of U.S. narcotics raw materials import policy. The authors are Professors of Economics at New York University and Princeton University respectively.

SUMMARY

This report provides an economic analysis of the so-called "80/20 rule" which requires at least 80% of U.S. narcotic raw material imports to come from India or Turkey. Our principal findings are the following:

- * Economic analysis indicates that the 80/20 rule cannot be expected to reduce the level of Indian stockpiles of opium. Neither can it be expected to reduce the variability of these stockpiles. These predictions of economic analysis are borne out in the available data, which show that Indian opium stockpiles have remained large despite the promulgation of the 80/20 rule.
- * The 80/20 rule leaves the U.S. vulnerable to monopolistic price increases for narcotic raw materials by India and Turkey.
- * The 80/20 rule has not served a role in preventing or reducing the diversion of narcotic raw materials into the illicit market. To the contrary, it may have reduced the security of narcotic raw materials supplies by shifting demand to less secure suppliers.

I. Introduction

United States policy with regard to the importation of narcotics raw materials is intended to promote several policy objectives simultaneously. The primary objectives of our narcotics importation policies are: (1) Assuring a reliable supply of narcotics raw materials at reasonable prices for legitimate medical and scientific applications in the United States, and (2) Preventing the diversion of narcotics raw materials into the illicit market, either here in the U.S. or abroad.

Our primary objective in this report is to demonstrate, on the basis of economic analysis, that the so-called "80/20 rule" has served neither of the primary policy objectives stated above. This rule requires that at least 80% of the narcotic raw material imported into the United States each year shall have as its original source Turkey or India. Contrary to U.S. policy goals, the rule has reduced the reliability of foreign sources of narcotics raw materials and may even have exacerbated the problem of diversion of these materials into illicit channels. The rule also reduces the flexibility of U.S. importers and leaves them vulnerable to possible monopolistic price increases by Turkey and India in the future.

II. The Original Justifications for the 80/20 Rule

The 80/20 rule was originally promulgated as a way of supporting "traditional suppliers" of narcotic raw materials in reducing stockpiles of opium and concentrate of poppy straw (CPS) while preventing diversion into the illicit market. It was hoped that the rule would serve this function without disrupting the legitimate importation of narcotics raw materials.

The rule was meant to reduce and stabilize Indian and Turkish stockpiles of narcotic raw materials. Indian stockpiles of opium gum are especially a concern, since opium gum can easily be channeled into the illicit market. When Indian stockpiles are large, the potential for diversion onto the illicit market is greater.

This objective is certainly desirable and reflects quite legitimate concerns associated with the importation of narcotic raw materials. As we shall demonstrate, however, economic analysis suggests that the 80/20 rule has not been, and cannot be expected to be, successful in achieving this goal. Furthermore, all the available evidence confirms that the 80/20 rule has not operated in the way that was intended.

III. The Economic Effects of the 80/20 Rule: Analysis

The basic economic effect of the 80/20 rule is to provide an assured source of demand for Indian or Turkish producers. These countries will capture at least 80% of the business from the U.S., quite apart from the basic economic forces operating either in Turkey, India, the United States, or the world market for narcotic raw materials. For example, even if countries other than Turkey and India are more efficient at producing narcotic raw materials, those countries combined share of the U.S. market cannot exceed 20%.

The central question regarding the efficacy of the 80/20 rule is this: can the rule, by providing an assured source of demand for Turkey and India, in fact be expected to reduce and stabilize Indian opium stockpiles? We consider these questions in turn in the following two subsections.

A. The 80/20 Rule Has Not and Will Not Reduce Stockpiles of Indian Opium

A naive view would suggest that by increasing the demand for Indian opium, the 80/20 rule would reduce Indian stockpiles of opium. This logic may have been behind the 80/20 rule to begin with. Unfortunately, this reasoning totally excludes the supply side of the market.

In fact, there is no reason to expect the 80/20 rule to

systematically lower the average size of Indian stockpiles. Remember that the 80/20 rule operates solely on the demand side of the market; it is meant to increase U.S. demand for Indian opium. There is nothing in the 80/20 rule that keeps production below sales, however, as is required if stockpiles are to shrink.

Stockpiles represent the excess between supply and demand. Simple accounting tells us that the size of the Indian stockpile in any given year is determined by the following factors:

- a. the stockpile inherited from the prior year
- b. the acreage planted, yield, and thus total production of opium in India during the current year
- c. the quantity of Indian opium sold during the current year.

The stockpile grows if the total current production exceeds current opium sales, and shrinks otherwise.

If we write S_t for the size of the stockpile at the end of year t , P_t for the total production of opium during year t , and D_t for the total amount demanded (sold) during that year, then the size of the stockpile varies over time according to the following rule:

$$S_t = S_{t-1} + P_t - D_t.$$

For example, during the year 1988 this equation states that $S_{1988} = S_{1987} + P_{1988} - D_{1988}$, that is, the stockpile at the end of 1988 is equal to the previous year's stockpile (S_{1987}) and the difference between 1988 production (P_{1988}) and sales (D_{1988}).

This accounting relationship tells us that the only way to systematically reduce the size of stockpiles over time is to have sales in excess of total production: S_t is less than S_{t-1} provided that D_t is greater than P_t .

At this point we shall focus on the movement over time of the expected or average size of the stockpile. This emphasis is appropriate for determining whether the 80/20 rule can systematically reduce the overall size of Indian stockpiles. We therefore shall restrict our attention at this point to expected (average) demand and expected (average) production, as distinct from actual or realized demand and production. Below we shall consider the variability of stockpiles and ask whether the 80/20 rule reduces this variability.

Given the presence of the 80/20 rule, the movement over time of Indian stockpiles depends heavily on the supply policies adopted by India, in particular on Indian planting policies. Only if these policies are specifically and systematically designed to yield less than will be purchased in the future can stockpiles be expected to fall.

It is not absolutely clear what policy India uses to determine the acreage planted for opium, but it is our

understanding that the following rule is a good approximation to the one actually used by the Indian authorities. In each year, enough poppies are planted to produce (on average) an amount of opium equal to the quantity sold in a peak year. If we label this peak demand by D , then average production in a given year, year t , is P_t , which equals D . With this planting rule, the expected or average size of the Indian stockpile changes over time according to the simple formula

$$S_t = S_{t-1} + D - D_t$$

This simple relationship is quite instructive. It tells us that stockpiles will fall over time only if demand is greater than previous peak demand, that is, only if the demand in year t , D_t , exceeds the previous peak demand, D .

What does this analysis imply about the effect of the 80/20 rule on Indian stockpiles? The rule could reduce stockpiles only if (1) the rule actually increased the demand for Indian opium when it was introduced, and if (2) India did not adjust its planting policies to reflect this increase in demand. If these conditions were met, the 80/20 rule would have had an immediate effect to lower stockpiles. The reduction in stockpiles would equal the magnitude of the unexpected increase in demand for Indian opium. Even under these conditions, after this initial effect the continued presence of the rule would have no impact on the size of the

stockpiles.

Economic analysis indicates, however, that the 80/20 rule would not in fact increase the demand for Indian opium. As discussed at greater length below and in the submission of First State Chemical Company, the demand for opium is largely dependent upon manufacturers' need for noscapine (and to a lesser extent, thebaine). During periods when the price of noscapine is high, the demand for opium also is high, with or without the 80/20 rule. And during period when the price of noscapine is low, the demand for opium is low, despite the 80/20 rule; U.S. importers can simply shift their purchases to Turkish CPS.

In summary, while India may have believed that the 80/20 rule would result in a one-time reduction in Indian stockpiles after it went into effect, in fact no such effect can be expected on the basis of economic analysis, since U.S. manufacturers based their opium purchases on their needs for noscapine and thebaine. Economic reasoning therefore suggests that the 80/20 rule would be ineffectual in reducing Indian opium stockpiles.

B. The 80/20 Rule Does Not Stabilize Indian Stockpiles

We have just argued that the 80/20 rule cannot be expected to reduce the average level of Indian stockpiles over time. Is there any reason to expect it to reduce the variability of these stockpiles?

The mathematical measure of variability is called variance. The variance of the Indian stockpile measures the size of its deviations about its average size. Going back to our basic equation determining the movement of Indian stockpiles over time, we have

$$S_t = S_{t-1} + P_t - D_t.$$

Variability in the stockpiles derives from variability in total production (supply uncertainty) and variability in total sales (demand uncertainty). Since entirely different factors affect supply and demand (see below), it is reasonable to assume that these two sources of uncertainty are unrelated (uncorrelated). Therefore, basic statistics tells that the variance of the stockpile equals the variance of total production plus the variance of sales.¹

What effect does the 80/20 rule have on these variances? Quite clearly, the 80/20 rule has no effect on the variability of total production in the Indian opium industry, which is primarily a function of the government-approved hecterage levels and local weather conditions.²

1. Denote by σ^2_S the variance of the size of the stockpile. If there is no correlation between supply shocks and demand shocks, basic statistics tells us that $\sigma^2_S = \sigma^2_P + \sigma^2_D$, where σ^2_P and σ^2_D are the variances of the quantity produced and the quantity demanded respectively.

2. If anything, the 80/20 rule will increase the variability of total production, as more hectares are planted to serve the perceived increased demand.

So, the only way that the 80/20 rule could possibly stabilize Indian stockpiles is by reducing the variability of demand. We must examine the demand for Indian opium more closely in order to analyze the effect of the 80/20 rule on its variability.

The quantity of Indian opium sold depends on the following factors:

- a. overall world demand conditions for narcotic raw materials, as reflected in the world price of concentrate of poppy straw.
- b. demand conditions in the U.S.
- c. the current price charged by India for its opium, especially in comparison with the world price of CPS
- e. the world price of noscapine and the U.S. demand for thebaine.

To understand why demand for Indian opium has not been stabilized by the 80/20 rule requires an appreciation of the importance of products derived from the opium, in particular noscapine and thebaine. Both noscapine and thebaine are natural by-products of opium. Although there is no significant demand for noscapine in the United States, it is at times in great demand on the world market. Because of the significance of these derivative products for the demand for Indian opium, the 80/20 rule, in conjunction with Indian pricing policies, has actually had a destabilizing effect on Indian stockpiles.

To give a sense of the importance of noscapine and

thebaine, consider the following financial calculations, which are approximately accurate in today's market. One ton of opium sells for about \$35,000 delivered. This ton will yield about 50 kilograms of noscapine, which sells on the world market for about \$350 per kilogram for a total of \$17,500. In addition, the ton of opium will yield about 10 kilograms of thebaine, which has a U.S. market value of \$550 per kilogram for a total of approximately \$5500. Thus, one ton of opium will yield about \$23,000 return from noscapine and thebaine. Two-thirds of the value of the opium comes from these derivative products.

How do these facts bear on the demand for Indian opium? Currently, the only source in the world for noscapine is Indian opium: it is not contained in concentrate of poppy straw.³ Basic economics tells us that the demand for Indian opium will rise when noscapine and thebaine are highly priced, but the demand for Turkish CPS will not go up under those conditions. So, buyers will shift to Indian opium when the price of noscapine and thebaine are high, and they will shift to Turkish CPS when these derived products are relatively inexpensive on the world market.⁴

Evidently, movements in the world market prices of

3. Indian opium contains morphine, codeine, thebaine and noscapine. Turkish CPS contains morphine and codeine, and Australian and French CPS contains morphine, codeine and thebaine.

4. Another factor affecting the relative demand for opium and CPS is that CPS is much more economical to process and has less of an environmental impact than opium.

noscapine and thebaine create variability in the demand for Indian opium relative to Turkish CPS. This variability is exacerbated by the pricing policies adopted by the Indian authorities: they do not adjust prices to reflect changes in the world price of noscapine or thebaine. Under these conditions, demand for Indian opium is inevitably quite variable. This variability in turn translates into fluctuating stockpiles.

The relative demand for opium and CPS is extremely volatile. Currently, noscapine has a relatively low price and Turkish CPS supplies are also relatively low. The demand for Indian opium is declining, and stockpiles are growing. As the price of noscapine has declined, so too has the demand for Indian opium. Buyers of narcotic raw materials from all countries, including the U.S., have shifted to CPS. U.S. buyers have largely shifted to Turkish CPS, as required by the 80/20 rule, but the rule will hardly prevent Indian stockpiles from growing. This undesirable outcome will be all the more pronounced if Turkish production and yield of CPS are high.

In summary, at present relative price levels for opium and CPS, the most important source of variability in the demand for Indian opium is the world price of noscapine. The 80/20 rule does nothing to reduce this source of variability in demand. Consequently, the rule cannot be expected to stabilize Indian stockpiles. Given the importance of derivative products in the demand for Indian opium, and given Indian pricing policies, the

80/20 rule is totally ineffectual in stabilizing the demand for Indian opium.

C. The 80/20 Rule Leaves the U.S. Vulnerable to Monopolistic Price Increases by India and Turkey

The 80/20 rule increases India's and Turkey's market power. By market power economists mean their ability to raise price without suffering a loss of business. Market power is measured by the elasticity of demand, which is defined as the percentage loss of business the supplier would suffer if it were to raise price 1%. A low elasticity of demand indicates that a price increase will not cause much loss of business, so the supplier has significant market power.

Since narcotics are used largely in medical and scientific applications, and since there are few if any good substitutes for narcotics in most applications, the elasticity of demand for narcotic raw materials is naturally quite low. In other words, buyers are relatively insensitive to price.

In a competitive market, buyers typically will not pay more just because their demand is inelastic. Competition among sellers will drive prices down to supply costs. For example, even though the demand for food is very inelastic, competition among supermarkets and other suppliers of food keeps price down.

Buyers with inelastic demands are much more vulnerable if there is only minimal competition among suppliers. If all

residents in one community were required to purchase all of their food from a single store, or from only two stores, those stores would wield considerable market power and prices could be expected to rise above competitive levels. Even if residents were only required to purchase 80% of their food from the required stores, prices at those stores would still rise markedly.

This is exactly the situation in which the United States places itself with respect to narcotic raw material imports. Both India and Turkey face less elastic demand on account of the 80/20 rule, and together they face greatly reduced elasticity of demand. In other words, each would lose far less in sales, were it to raise its price, than in the absence of the 80/20 rule. And if they were to raise prices together, they could not lose much of their U.S. business, no matter how high their price was: they would still capture 80% of U.S. demand for imports. India and Turkey could raise their prices -- either individually or jointly -- and U.S. importers would have little choice but to continue to purchase from them.

Our vulnerability to price increases is even more pronounced if these countries were to adopt a policy of price discrimination by charging higher prices for U.S. buyers than for others. Again the supermarket analogy is a good one. Suppose that senior citizens of the community are required to purchase from a particular store, but others are free to shop around. Suppose further that the store can distinguish senior

citizens from other shoppers and charge senior citizens a higher price. If such price discrimination is possible, there is even a greater incentive for the supermarket to raise price for senior citizens than in the absence of price discrimination, and the price paid by senior citizens can be expected to rise by even more.

This analysis warns us that the 80/20 rule leaves the United States in a potentially vulnerable position by turning U.S. importers into captive buyers. If Turkey and/or India were to choose to set its narcotic raw materials prices with the aim of increasing or maximizing its profits, U.S. importers would have to pay these higher prices rather than seek less expensive supplies elsewhere.

Available evidence indicates that neither India nor Turkey has yet exploited the market power created by the 80/20 rule. This is fortunate for the U.S., but continues to leave us in a vulnerable position. We are subject to a supply shock, just as when OPEC raised the price of oil unexpectedly during the 1970s. So long as we have limited sources of supply -- in this case by our own regulation -- we will remain vulnerable. And the 80/20 rule perpetuates this vulnerability by discouraging alternative sources of supply, even quite secure ones, from serving U.S. importers because they are limited to a total of 20% of the market.

D. The 80/20 Rule Alone Cannot be Expected to Increase the Security of Narcotics Supplies

Nothing in the 80/20 rule actually inhibits or directly discourages diversion onto the illicit market. Increased security can only come from supplier countries applying strict controls over production. As reported by the International Narcotics Control Board and other sources, there have been significant recent seizures of Indian-origin opium and heroin.

It is possible that the 80/20 rule may exacerbate security problems. The rule shifts demand from the most secure suppliers -- like Australia -- to the less secure ones-- namely India. This shift directly reduces the security of supplies. It also rewards those countries that have not made their supplies secure, and penalizes those that have developed good security records.

IV. The Economic Effects of the 80/20 Rule: Evidence

We now briefly comment on the available evidence to show how the data bear out the theoretical reasoning and predictions outlined above. Our main sources of data are the annual "Report of the International Narcotics Control Board" of the United Nations for the years 1976-1988, including the special 1985 report "Demand and Supply of Opiates for Medical and Scientific Needs." Here we shall examine these data to see if

the stated objectives of the rule have been promoted since its inception.

A. The 80/20 Rule Has Not Reduced the Size of Indian Stockpiles

Stockpiles of opium and CPS are no longer escalating as they did during the 1970s. The primary reason is that in 1980 "the principal producing countries agreed to reduce the areas used for poppy cultivation. Thereafter, total production of opiate raw materials has been in approximate balance with global consumption of opiates. Projection for 1989 indicates that the balance will be maintained." (INCB 1988 Report, p.10).

Of course, since the 80/20 rule was not even in effect in 1980, we cannot attribute any current balance of production and consumption to the rule. Unfortunately, there has been no success during the 1980s in systematically reducing the stocks inherited from the 1970s. Indeed, it is clear that Indian stockpiles have not declined as was intended by the rule.

The various INCB annual reports indicate that the end-of-year Indian stockpiles of opium, as measured first in tons of opium and then in morphine equivalent tons, took on the following values:

Year	Tons of Opium	Morphine-Equivalent Tons
1983	2665	293
1984	2207	243
1985	2116	233
1986	2062	227
1987	2257	248

The current stockpile exceeds the entire annual world demand for opiates.

The only significant reduction in Indian stockpiles occurred during 1984, and was the result of an extremely low yield due to poor weather conditions. There is simply no reason to believe that the 80/20 rule has had any beneficial impact in reducing Indian stocks of opium.

In fact, 1987 demonstrates exactly the type of failure of the 80/20 rule that our analysis above predicted. The reason for the increase in Indian stockpiles was a marked drop in exports of opium to 505 tons, the lowest level since 1981. The United States, which is the largest importer of Indian opium, imported only 181 tons (in comparison with an average level of imports of 340 tons over the previous five years). How could this happen despite the 80/20 rule? The reduction in demand for noscapine caused U.S. importers to shift their demand to Turkish CPS, just as described in our analytical section above.

B. The 80/20 Rule Has Not Prevented Large Fluctuations in the Size of Indian Stockpiles

The data presented above indicate that the major sources of variation in Indian stockpiles are variations in production levels due to government decisions on planting and weather conditions, and variations in the demand for Indian opium due

to the fluctuating price of noscapine. As it happened, yields were very low in 1984 so stockpiles decreased during that year, and the demand for noscapine was weak during 1987 so stockpiles rose during that year. In neither case did the 80/20 rule have a stabilizing effect. In particular, during 1987 the 80/20 rule did not prevent U.S. buyers from nearly halving their demand for Indian opium.

C. The 80/20 Rule Has Not Increased the Security of Narcotic Raw Materials

There is no evidence that the 80/20 rule has caused India to increase its enforcement activities to limit diversion to the illicit market.

Such evidence as is available suggests that India is a relatively insecure supplier of narcotic raw materials. The 1988 INCB report, for example, notes that a great deal of opium has been seized in India, and most of it is of domestic origin (p.14). The report states that Turkey is no longer a producer of opium, but is a transit point for the trafficking of heroin (p.16). There certainly is no evidence that the 80/20 rule per se has increased the security of narcotic raw materials supplies.

In contrast, suppliers not favored by the 80/20 rule are more secure than are either India or Turkey (as a transit country). A notable example is Australia, which is very likely the most secure in the world. This suggests that the 80/20

rule has reduced rather than increased the security of our narcotic raw materials supplies.

D. The 80/20 Rule Has Rewarded Inefficient Suppliers at the Expense of Efficient Ones

The 80/20 rule prevents efficient facilities, such as those in Australia, from supplying U.S. buyers' needs. In a normal competitive market, lower-cost producers will capture business at the expense of their less efficient rivals. The 80/20 rule prevents this natural process from operating, by propping up such government-subsidized high-cost suppliers as Turkey. This rule has the effect of protecting and encouraging less efficient suppliers. This in turn may harm U.S. importers, who will ultimately pay for this inefficiency if government subsidies are ever withdrawn or reduced.

It is our understanding that both Turkey and India are currently operating at a loss. This is strong evidence that their costs are higher than other suppliers.

As noted above, the rule also increases the market power of Turkey and India over U.S. buyers. If either of these countries ever chooses to raise the price charged for U.S. buyers -- as indeed would be in their interests as a way of attracting foreign exchange -- U.S. buyers would be at their mercy.⁵ The

5. We recognize that Turkish and Indian export prices have been set with objectives other than profit maximization. But these objectives, such as protecting farmers who cultivate poppies, are not inconsistent with either country exploiting the market power that the 80/20 rule confers on it.

price paid by scientific and medical users of narcotics could rise markedly.

V. Conclusions: The 80/20 Rule Has Not Achieved its Goals, and
Has Had Significant Adverse Effects

The 80/20 rule has neither reduced or stabilized Indian stockpiles of opium. Nor has it stabilized the demand faced by "traditional suppliers." During 1987, for example, U.S. importers shifted away from India due to weak demand for noscapine, and the rule did nothing to prevent Indian stockpiles from rising by over 20 tons of morphine equivalent.

The rule also has failed to encourage or reward those suppliers whose operations are most secure or efficient. To the contrary, the rule shifts production away from the most efficient and most secure suppliers.

**APPENDIX 4.—ATTACHMENTS TO THE STATEMENT OF LLOYD W.
NYSTROM, BUSINESS DIRECTOR, MEDICINAL NARCOTICS,
MALLINCKRODT, INC., SPECIALITY CHEMICALS CO., ST. LOUIS, MO**

ATTACHMENTS

- Attachment I - Letter and Resume from Dr. K.M. Foley
Sloan-Kettering Cancer Center
- Attachment II - Letter from Dr. P.S. Portoghese
University of Minnesota
- Attachment III - Area Licensed and Opium Production
Government of India
- Attachment IV - Minimum Qualifying Yield
Government of India
- Attachment V - Extracts from Indian law relating to
Poppy Cultivation - Government of India
- Attachment VI - The Gazette of India, September 6, 1988
Prevention of Illicit Traffic
- Attachment VII - The Gazette of India, September 16, 1985
Narcotic Drugs Act
- Attachment VIII - Joint Media Statement, 25 May 1988
and Pharmaceuticals Benefits Pricing Authority
Guidelines for Pharmaceuticals Pricing
Arrangements
- Attachment XI - Historical Analysis of the "80-20" Rule
Jane Lang, Esq.

ATTACHMENT I



*Chief, Pain Service
Department of Neurology*

TO: Mr. James Elder
Mallinckrodt, Inc.

FRDM: Dr. Kathleen M. Foley

RE: The Omnibus Drug Initiative Act of 1988

The Omnibus Drug Initiative Act of 1988 requests a review of the United States Narcotic Review Material Policy. As part of this review, a critical question to be answered is what might be the impact on patient therapy if other products were substituted for opium. These other products would specifically be the synthetic narcotics, currently available. In order to address this question, it is useful to review the existing expert opinions that were rendered on this subject in the early 1970's. Dr. William Beaver reviewed exactly this question in his paper "Are Synthetic Narcotics Adequate Substitutes for Opium-Derived Alkaloids" and a copy of this paper is included for review. (1) In brief, Dr. Beaver's careful analysis continues to be very current. He specifically urged that the U.S. Government strongly reject any policy that would restrict the availability of the opium derived alkaloids for legitimate medical and scientific use.

Similarly, in the 1975 published report entitled "Synthetic Substitutes for Opiate Alkaloids", Drs. Joseph Cochin and Louis Harris summarized the deliberations of their meeting with the following statement, "The research efforts of a large number of medicinal chemists, pharmacologists, and clinicians have provided a variety of new analgesic agents some with lessened dependence-producing liability. However, it is important to note in this regard that no agent as potent and efficacious as morphine but with significantly lower abuse potential has been developed. None of the synthetic agents has any real therapeutic advantage over the natural products and many are not as good." (p. 40) (2)

This statement continues to hold true in 1989. What has changed most significantly since these reports were prepared is a better understanding of the neuropharmacology of pain and the broader use of opioid analgesics as the mainstay of treatment for acute pain and for certain chronic pain states. The World Health Organization, the International Association for the Study of Pain, the American Medical Association, the American College of Physicians and the American Pain Society have all strongly supported the tenet that "opioid analgesics are the mainstay of therapy for patients with acute and certain types of chronic pain." (3)

*Memorial Sloan-Kettering Cancer Center
1275 York Avenue, New York, New York 10021
212 794-7050
MSKCC NYKTLX 64 9169*

Concurrent with this definitive policy have been more detailed studies in the use of opioids in clinical practice. The opioid drugs are used as 1) preanesthetics, 2) perioperatively for balanced anesthesia, 3) postoperatively for pain management, 4) for acute and chronic pain management of cancer pain and 5) for treatment of certain chronic non-malignant pains. These drugs are also used to treat apatency in patients with paraplegia, and for restless leg syndrome. The opioids have also been the major treatment approach for cough and diarrhea. In this discussion, I would like to emphasize the use of opioids for pain management and to stress that, in 1989, we know more than was known in 1975 when the previously described reports were published. This new knowledge has changed our perspective on the synthetic drugs and has pointed up the fact that they have assumed less importance to pain management especially chronic pain management. For example, meperidine--which was noted in the 1975 AMA Survey on prescription drugs as the most widely used drug by physicians in the U.S., is a synthetic alkaloid, and is problematic. We have learned that meperidine has a toxic, active metabolite.⁽⁴⁾ This active metabolite normeperidine, can accumulate in patients receiving meperidine and produce central nervous system hyperirritability characterized by subtle mood effects, tremors and seizures. This data has led to the more restricted clinical use of meperidine and it is a drug that should not be used to manage chronic pain.

Similarly, the development of sophisticated pharmacokinetic analyses have now allowed us to recognize that synthetic drugs, like levorphanol and methadone, have very long plasma half-lives. These pharmacokinetic observations make these drugs less useful in the care of elderly patients with pain, as well as potentially more dangerous because of drug accumulation. (5)

Another important observation is the recognition that the mixed agonist-antagonist drugs are readily abused and do not offer a useful alternative to chronic pain management because increasing doses are associated with psychotomimetic effects. (5)

Of particular importance, the WHO Cancer Unit as part of its Freedom from Cancer Pain Program has requested that oral morphine be listed on the essential drug list and recognized as the drug of choice for the management of chronic cancer pain. No drug has demonstrated itself to be more effective for the management of chronic cancer pain. At the current time, the WHO member countries have been asked to introduce a national health policy for cancer pain to make oral morphine available for this group of patients. Enclosed is the WHO booklet addressing these issues and formulating the current guidelines for care of cancer pain patients worldwide. This is a very important program with enormous worldwide support and any considerations by the State Department must recognize how vital opioids are for the control of pain in this population of patients. In fact, during the last 7 years, the growing need to appropriately treat cancer pain has been recognized and sadly it is being thwarted by a strong antidrug policy which enormously impacts on the availability and use of prescription opioid drugs for patients with cancer pain. Such policies are currently limiting patients worldwide to access to appropriate pain medications because of an overriding concern for drug addiction.

As it has become apparent that opioid drugs are needed to manage chronic cancer pain, there has been a reawakened interest in using morphine orally as the drug of choice. Historically, morphine was only used parenterally (by injection) because of its poor oral bioavailability. However, it is now recognized that oral morphine is very effective when appropriate dosing is

used. Also of particular interest, we have identified that morphine too has an active metabolite, morphine-6-glucuronide, which is 20 to 100 times more potent than morphine. This information sheds new light on morphine's role in pain management.

New approaches in drug delivery have also influenced the usefulness and role of numerous agents again with morphine remaining the opioid of choice for the administration of drugs epidurally or intrathecally.

Drugs that are derived from thebaine, specifically naloxone and naltrexone, remain irreplaceable as relatively pure opioid antagonists. They are used widely in emergency rooms for reversal of opioid overdose, and with the much greater use of opioid anesthesia, these drugs, specifically naloxone, have become the drugs of choice to reverse these "anesthetic" doses. Approximately 25% of general anesthesia in the U.S. employs naloxone for its reversal, making this an essential opioid.

Similarly, oxycodone is an important first line drug for the management of mild to moderate pain of an acute or chronic nature. This drug is widely used as a safe and effective analgesic and as an important alternative to codeine. Patients unable to tolerate codeine can tolerate oxycodone and report effective pain control. Physicians are well versed in its pharmacologic profile and it has an important place in clinical practice between the non-opioids and the strong opioids.

The recent advances in our understanding of the neuroscience of pain, specifically, the neuropharmacology of pain, and in the pharmacologic profiles of the standard and newer opioid analgesics, have improved the care of patients with pain. There is a critical need for these drugs to be available and any U.S. policy must recognize the role of these drugs in the care of patients with pain. Before any decisions are considered, expert testimony from numerous medical groups and associations is in order to discuss these issues at length. Such groups include the:

- American Medical Association
- American Society of Clinical Oncology
- American Pain Society
- NIH Interagency Committee on Pain
- American College of Physicians
- American Society of Clinical Pharmacology & Therapeutics
- Committee on Problems of Drug Dependence
- International Association for the Study of Pain
- World Health Organization's Cancer Unit
- U.S. Cancer Pain Relief Committee
- Drug Enforcement Agency
- National Institute of Drug Abuse
- Society for Neuroscience

REFERENCES

1. Beaver WT: Are synthetic narcotics adequate substitutes for opium-derived alkaloids. *Advances in Neurology*, Vol. 4, Raven Press, New York, 1974.
2. Cochlin J, Harris L: Synthetic substitutes for opiate alkaloids. *Drug Abuse Council, Inc.*, 1975.
3. Foley KM: The treatment of cancer pain. *New Engl J Med*, 313:84-95, 1985.
4. Kaiko RF, Foley KM, Grabinski PY, et al: Central nervous system excitatory effects of meperidine in cancer patients. *Ann Neurol*, 13:180-185, 1979.
5. Foley KM, Inturrisi CE: (Eds.) *Advances in Pain Research and Therapy*, Vol. 8: Opioid Analgesics in the Management of Clinical Pain. Raven Press, New York, 1986.

Name: Kathleen M. Foley, M.D.
 Date of Birth: January 28, 1944
 Place of Birth: Flushing, New York
 Nationality: U.S. Citizen
 Education: St. John's University
 1961-1965, B.A. (Biology) magna cum laude, New York City
 Cornell University Medical College
 1965-1969, M.D., New York City
 Postdoctoral Training: Intern
 1969-1970, Medicine, The New York Hospital
 Fellow
 1970-1971, Genetics-Department of Medicine, N.I.H.
 Genetic Training Grant, The New York Hospital
 Resident
 1971-1974, Neurology, The New York Hospital
 Special Fellow
 1975-1978, Neuro-Oncology, American Cancer Society
 Memorial Sloan-Kettering Cancer Center
 Positions and Appointments: Hospital Appointments
 1974-1979, Assistant Attending Neurologist, Neurology Department, Memorial Sloan-Kettering Cancer Center
 1974-1979, Assistant Attending Neurologist, Neurology Department, The New York Hospital
 1974-1983, Attending Neurologist, Manhattan Eye & Ear Hospital
 1975-1979, Visiting Assistant Physician, Consultant in Neurology, Rockefeller University Hospital
 1979-1988, Associate Attending Neurologist, Neurology Department, Memorial Sloan-Kettering Cancer Center
 1988-Present, Attending Neurologist, Neurology Department Memorial Sloan-Kettering Cancer Center
 1979-Present, Associate Attending Neurologist, Neurology Department, The New York Hospital
 1979-Present, Visiting Associate Physician, Rockefeller University Hospital, Consultant in Neurology
 1982-Present, Consultant, Calvary Hospital
 1982-Present, Chief--Pain Service, Department of Neurology Memorial Sloan-Kettering Cancer Center

Teaching/Research Appointments
 1974-1975, Instructor in Neurology
 1975-1979, Assistant Professor of Neurology
 1979-Present, Associate Professor of Neurology
 1979-Present, Associate Professor of Pharmacology,
 Cornell University Medical College
 1981-1984, Research Associate, Laboratory of Neuro-
 Oncology, Sloan-Kettering Institute for Cancer Research
 1985-1988, Associate Member, Memorial Sloan-Kettering
 Cancer Center
 1988-Present, Member, Memorial Sloan-Kettering Cancer
 Center

Licensed
 Physician: Year: 1970 Place of Issue: New York Number: 106794-1

Board
 Certification: Year: 1977 Name: American Board of Psychiatry &
 Neurology

Scientific &
 Medical Societies:

American Academy of Neurology
 American Federation for Clinical Research
 American Medical Association
 American Neurological Association
 American Pain Society
 American Society of Clinical Oncology
 American Women's Medical Association
 Cornell University Medical College Alumni Association
 Eastern Pain Association
 Harvey Society
 International Association for the Study of Pain
 New York Academy of Sciences
 Society of Neuroscience

Honors & Awards:

Balfour M. Mount Award, American Journal of Hospice Care,
 1988
 Bristol-Myers Unrestricted Grant Program for Pain
 Research, 1988-1992
 Annie Blount Storrs Award, Calvary Hospital, 1988
 William M. Witter Award & Lecture, University of
 California-San Francisco, 1987
 Outstanding Woman Scientist, Association for Women
 in Science, Metropolitan New York Chapter, 1987
 National Board Award of The Medical College of
 Pennsylvania, 1986
 John J. Bonica Award of Eastern Pain Association, 1986
 Louise & Alston Boyer Award in Clinical Science, 1983
 Rita Allen Scholar, 1979-1983
 American Cancer Society Junior Faculty Award, 1975-78
 National Foundation Student Award for Research, 1968
 Alpha Omega Alpha, Cornell University Medical College, 1968
 George S. Meister Prize in Pediatrics, Cornell University
 Medical College, 1969

Other Activities: Committees, Intramural MSKCC
 Pain Management Task Force
 Do Not Resuscitate Task Force
 Ambulatory Care Committee
 CCOP Advisory Group
 Investigational Drug Committee
 Ad Hoc Committee on Clinical Competency
 Thoracic Task Force
 Standards, Pharmacy and Dietary
 Subcommittee to Review Graduate Training Programs in
 Medical Oncology and Hematology Oncology

Committees, Cornell
Admissions, 1980-84
 Board of Directors, Alumni Association
 Alumni Association, Nominating Committee
 Council of Office of Women in Medicine
 Curriculum
 Women in Medicine

Committees, Extramural
 Board of Directors, International Pain Foundation, 1988-
 Board of Directors, American Pain Society, 1980-1982
 President Elect, American Pain Society, 1983-1984
 Chair, Nominating Committee, American Pain Society, 1986
 Bylaws Committee, American Pain Society, 1986-87
 Examiner, American Board of Psychiatry & Neurology, 1980-
 Member, AMA Ad Hoc Advisory Panel on Management of Chronic
 Pain
 Member, Pain Management Information Center Advisory Board
 Special Consultant, National Cancer Institute Division of
 Cancer Control, 1980-
 Special Consultant to Cancer Unit, World Health
 Organization
 Expert Advisory Panel on Cancer, World Health
 Organization, 1985-1989
 Councillor, International Association for the Study
 of Pain
 International Association for the Study of Pain
 Committees:
 Chairman, Ad Hoc Subcommittee on Education in
 Developing Countries and Coordination with WHO,
 1985-1987
 Education Committee, 1986-1987
 Ad Hoc Committee on Establishing an IASP Foundation,
 1986-1987
 Ad Hoc Subcommittee on Interprofessional Relations,
 1986-1987
 Ad Hoc Subcommittee on Refresher Courses, 1986-1987
 Ad Hoc Subcommittee on Educational and Teaching
 Materials (Commercial Resources), 1986-1987
 American Academy of Neurology, Continuing Education, 1984

American Neurological Association, Membership, 1984
 Councillor for American Neurological Association, 1984-
 Chairman, DHHS Commission on Disability and Pain, 1985
 Member, Committee on Science, Engineering and Public
 Policy Research Briefing Panel on Pain and Pain Control,
 National Academy of Science, 1985--
 American Academy of Neurology, Alternate Delegate to
 American Pain Society of the International Association
 for the Study of Pain, 1985-1987
 New York Academy of Medicine, Working Group on
 Prescription Drug Misuse, 1985
 American Medical Association, DATTA Reference Panel
 USP Neurological and Psychiatric Disease Advisory Panel,
 1985-1990
 Member, Committee of Problems of Drug Dependence
 Chair, Investments Sub-Committee of the Committee of
 Problems of Drug Dependence, 1986-87
 Member, Budget and Finance Sub-Committee of the Committee
 of Problems of Drug Dependence, 1986-87

Editorial Boards

Cephalgia, 1980-1985
 Clinical Journal of Pain, 1985-1987
 The Pain Clinic, 1988
 Journal of Pain and Symptom Management, 1987

Ad Hoc Reviewer

Science
 New England Journal of Medicine
 Clinical Pharmacology and Therapeutics
 Pain
 Annals of Internal Medicine
 Neurology
 Journal of the American Medical Association
 PRN Forum
 Archives of Internal Medicine
 Cancer

Home Address: 1 East End Avenue Tel. #: 988-5910
 New York, New York 10021

Office Address: 1275 York Avenue Tel. #: 794-7050
 New York, New York 10021

Social Security #: 134-34-9497

Marital Status: Married Spouse: Charles T. Foley

Dependents #: Two

Military Service: None

ABSTRACTS

1. FOLEY KM, POSNER JB: Pseudotumor cerebri and the empty sella syndrome. *Neurology* 24: 358, 1974.
2. FOLEY KM, WOODRUFF JM, POSNER JB: Radiation-induced malignant schwannomas. *Neurology* 25: 354, 1975.
3. FOLEY KM: Is benign intracranial hypertension a chronic disease? *Neurology* 27: 388, 1977.
4. FOLEY KM, ROGERS A, HOUE R: Pain in patients with cancer: a quantitative reappraisal. *Proc. Amer. Soc. Cancer Res.* 19: 357, 1978.
5. KAIKO R, FOLEY KM, INTURRISI C, HOUE RW: Normeperidine levels and CNS irritability in cancer patients. *Fed. Proc.* 37: 568, 1978.
6. FOLEY KM, KAIKO RF, INTURRISI CE, POSNER JB, LI CH, HOUE RW: Intravenous and intraventricular administration of beta-endorphin in man: preliminary studies. *Pain (Suppl 2)*, Second World Congress on Pain, IASP, S17, 1978.
7. KAIKO RF, FOLEY KM, HOUE RW, INTURRISI CE: Analgesic drug levels in cerebral spinal fluid and plasma in cancer patients. *Pain (Suppl 2)*, Second World Congress on Pain, IASP, S200, 1978.
8. FOLEY K, INTURRISI C, KOURIDES I, KAIKO R, POSNER JB, LI C: Intravenous and intraventricular administration of beta-endorphin in man: safety and disposition. *Proc. Int. Narcotic Res. Conf.: Characteristics and Function of Opioids*, Noordwijkerhout, The Netherlands, 23-27 July, 98, 1978.
9. KAIKO R, FOLEY KM, HOUE RW, INTURRISI CE: Narcotic levels in cerebral spinal fluid and plasma in man. *Proc. Int. Narcotic Res. Conf.: Characteristics and Function of Opioids*, Noordwijkerhout, The Netherlands, 23-27 July, 51, 1978.
10. YAO WT, HEIORICH G, FOLEY KM: The effectiveness of transcutaneous electrical stimulation (TNS) in chronic pain patients using narcotic analgesics. *Amer. Pain Soc.*, 35, 1979.
11. KANNER RM, FOLEY KM: Use and abuse of narcotic analgesics in a cancer pain clinic. *Amer. Soc. Clin. Onc.*, 21: 381, 1980.
12. MAX M, INTURRISI CE, GRABINSKI P, KAIKO RF, FOLEY KM: Epidural opiates: plasma and cerebrospinal fluid (CSF) pharmacokinetics of morphine, methadone and beta-endorphin. *Pain (Suppl 2)*, Third World Congress on Pain, IASP, S122, 1981.

13. KANNER RM, GALICICH JH, FOLEY KM: Patient selection of cordotomy in cancer pain. *Pain (Suppl 2)*, Third World Congress on Pain, IASP, S115, 1981.
14. INTURRISI CE, FOLEY KM, KAIKO RF, HOUE RW: Disposition and effects of intravenous (IV) methadone (MET) in cancer patients. *Pain (Suppl 2)*, Third World Congress on Pain, IASP, S99, 1981.
15. KANNER RM, FOLEY KM, GALICICH J: Patient selection for cordotomy in patients with cancer. *Neurology* 31: 45, 1981.
16. MAX MB, INTURRISI CE, GRABINSKI P, KAIKO RF, FOLEY KM: Epidural opiates: plasma and cerebrospinal fluid (CSF) pharmacokinetics of morphine, methadone, and beta-endorphin. *Neurology* 31: 95, 1981.
17. KANNER RW, MARTINI N, FOLEY KM: Epidural spinal cord compression in Pancoast syndrome (superior pulmonary sulcus tumor): clinical presentation and outcome. *Ann. Neurol.* 10: 77, 1981.
18. INTURRISI C, MAX M, UMANS J, SCHULTZ M, SHIN S, FOLEY KM, HOUE R: Heroin: disposition in cancer patients. *Clin. Pharmacol. & Therap.* 31:235, 1982.
19. KANNER RM, MARTINI N, FOLEY KM: Nature and incidence of post-thoracotomy pain. *Amer. Soc. Clin. Onc.*, 1: 152, 1982.
20. CASCINO TL, KORI SH, KROL G, FOLEY KM: CT scans of the brachial plexus in cancer patients. *Amer. Soc. Clin. Onc.*, 1: 5, 1982.
21. FOLEY KM, COOMBS D, MAX M, YAKSH T: Epidural and intrathecal opiates: basic studies and clinical correlates. *Amer. Pain Soc.*, 47, 1982.
22. JAECKLE K, YOUNG DF, FOLEY KM: The natural history of lumbosacral plexopathy in cancer patients. *Neurology*, 33: 67, 1983.
23. INTURRISI C, MAX M, FOLEY KM, HOUE R: Heroin: oral and parenteral pharmacokinetics in cancer patients. *Second World Congress on Clin. Pharm. Therap.*, 66, 1983.
24. PAYNE R, FOLEY KM, INTURRISI CE: Use of the chronic sheep preparation to study plasma-CSF pharmacokinetics of opiates. *Ann. Neurol.* 14: 138, 1983.
25. PAYNE R, FOLEY KM, INTURRISI CE: Plasma-CSF Pharmacokinetics of opiates. *Amer. Pain Soc.*, 71, 1983.
26. RAPOPORT S, STACY C, FOLEY KM: Median nerve somatosensory evoked potentials are useful in the diagnosis of metastases to the brachial plexus and adjacent spinal roots and epidural space. *Ann. Neurol.* 14: 143, 1983.
27. UMANS JG, KAIKO R, FOLEY KM, INTURRISI CE: Quantal bioassay of meperidine (Mep)-associated CNS excitation in man. *The Pharmacologist* 25: 127, 1983.

28. GRANEK I, ASHIKARI R, FOLEY K: The post-mastectomy pain syndrome. ASCO 3: 122, 1983.
29. PAYNE R, FOLEY KM, INTURRISI CE: Investigation of opiate pharmacokinetics in an animal model. Pain (Suppl 2), Fourth World Congress on Pain, IASP, S233, 1984.
30. INTURRISI CE, FOLEY KM, MAX M, CHEN J, SCHULTZ M, HOUE RW: Disposition and effects of heroin in pain patients. Pain (Suppl 2), Fourth World Congress on Pain, IASP, S204, 1984.
31. KAIKO RF, KANNER R, FOLEY KM, WALLENSTEIN SL, CANEL A, ANDERSON C, ROGERSAG, HOUE RW: Cocaine and morphine in cancer patients with chronic pain. Pain (Suppl 2), Fourth World Congress on Pain, IASP, S203, 1984.
32. MOULIN D, MAX M, KAIKO R, SI C, MAGGARD J, FOLEY K: The analgesic efficacy of Intrathecal (IT) D-Ala²-O-Leu⁵ Enkephalin (OADL) in cancer patients with chronic pain. Pain (Suppl 2), Fourth World Congress on Pain, IASP, S343, 1984.
33. FOLEY KM. Drug therapy of cancer pain. Pain (Suppl 2), Fourth World Congress on Pain, IASP, S199, 1984.
34. MOULIN OE, FOLEY KM, EBERS GC. Acute and chronic pain syndromes in multiple sclerosis (MS). Amer. Pain Soc., 49, 1985.
35. MOULIN OE, INTURRISI CE, MAGGARD J, FOLEY KM. The pharmacokinetics of continuous intrathecal infusions of morphine sulfate (MS) and O-Ala²-D-Leu⁵ Enkephalin (OADL)--results and implications. Amer. Acad. Neuro., 35: 92, 1985.
36. PORTENOY R, MOULIN O, FOLEY KM, INTURRISI CE, ROGERS A. Continuous intravenous infusion of opiates in cancer pain: review of 46 cases and guidelines for use. Amer. Soc. Clin. Onc., 4: 25, 1984.
37. MAUSKOP A, COYLE N, MAGGARD J, FOLEY KM. Continuous subcutaneous infusions of opiates in cancer patients with pain: safety and efficacy. Amer. Soc. Clin. Onc., 4: 39, 1985.
38. GRAUS F, KROL G, FOLEY KM. Early diagnosis of spinal epidural metastasis (SEM): correlation with clinical and radiological findings. Amer. Soc. Clin. Onc., 4: 269, 1985.
39. SUNDARESAN N, FOLEY KM, HILARIS B, MARTINI N. Neurological complications of superior sulcus tumors. Amer. Soc. Clin. Onc., 4: 189, 1985.
40. PORTENOY RK, JARDEN JO, SIOTIS JJ, LIPTON RB, KURTZBERG O, ROTTENBERG OA, FOLEY KM. Compulsive self-stimulation of nucleus ventralis posterolateralis (nVPL): studies of behavior, endocrine response, regional cerebral metabolic rate for glucose (rCMRglu), EEG and evoked potentials (EP's). Ann. Neuro., 18: 119, 1985.

41. MOULIN DE, INTURRISI CE, FOLEY KM. CSF pharmacokinetics of intrathecal morphine, methadone and D-Ala²-D-Leu⁵-Enkephalin (DADL) in cancer patients. *Int. Nar. Res. Coun.*, 2: 30, 1985.
42. MOULIN DE, MAX M, KAIKO R, INTURRISI, CE, MAGGARD J, FOLEY KM: Analgesic efficacy of intrathecal DADL enkephalin in cancer patients with chronic pain. *Ann. Neuro.*, 16: 124, 1984.
43. LAPIN J, KAIKO RF, ROGERS AG, WALLENSTEIN SL, FOLEY KM, HOUE RW: Cancer pain management with controlled-release oral morphine. *Amer. Pain Soc.*, 73, 1985.
44. FISHMAN 8, PASTERNAK S, WALLENSTEIN S, HOUE RW, FOLEY KM: The Memorial pain assessment card: A valid instrument for evaluation of cancer pain. *Amer. Pain Soc.*, 59, 1985.
45. MAUSKOP A, COYLE N, INTURRISI CE, MAGGARD J, FOLEY KM: Continuous subcutaneous infusion (CSCI) of narcotic analgesics (NA) in cancer patients with pain. *Amer. Pain Soc.*, 22, 1985.
46. MOULIN DE, FOLEY KM, EBERS GC: Acute and chronic pain syndromes in multiple sclerosis (MS). *Amer. Pain Soc.*, 88, 1985.
47. PORTENOY RK, INTURRISI CE, MAX M, COLBURN WA, MAGGARD J, FOLEY KM: Continuous intravenous infusion of methadone: pharmacokinetic and pharmacodynamic (PK-PD) relationships. *Amer. Pain Soc.*, 65, 1985.
48. BAILEY LM, COYLE N, FOLEY KM: The role of music therapy in cancer pain management. *Amer. Pain Soc.*, 80, 1985 .
49. BREITBART W, LOSCALZO M, MAUSKOP A, FOLEY KM: Short-term group therapy for out-patients with chronic non-malignant pain. *Amer. Pain Soc.*, 53, 1985.
50. PORTENOY RK, JARDEN JO, SIDTIS JJ, LIPTON R8, FOLEY, KM, ROTTENBERG DA: Compulsive self-stimulation of the nucleus ventralis posterolateralis: studies of behavior, endocrine response, regional cerebral metabolic rate for glucose, electroencephalogram, and evoked potentials. *Ann. Neuro.*, 18: 119, 1985.
51. PORTENOY RK, MOULIN DE, FOLEY KM, INTURRISI CE, ROGERS A: Continuous intravenous infusions of opiates in cancer pain: review of 46 cases and guidelines for use. *Amer. Soc. Clin. Onc.*, 4: 25, 1985.
52. FISHMAN 8, PASTERNAK S, WALLENSTEIN S, HOUE RW, HOLLAND J, FOLEY KM: The Memorial pain assessment card: a valid instrument for evaluation of cancer pain. *Amer. Soc. Clin. Onc.*, 5, 239, 1986)
53. PAYNE R, FOLEY KM: Exploration of the brachial plexus in patients with cancer. *Neurology*, 36 (Suppl. 1):329, 1986.

54. LOWENTHAL DA, SCHER H, MAUSKOP A, FOLEY KM: Prospective evaluation of 35 patients with prostatic cancer (PC) with suspected epidural spinal cord metastases (ESCM). *Amer. Soc. Clin. Onc.*, 5, 214, 1986.
55. MOULIN DE, FOLEY KM: Cancer pain at Memorial Sloan-Kettering Cancer Center (MSKCC) clinical characteristics and outcome. *Canadian Journal of Neurological Sciences*, Vol. 13 [3]:286-287, 1986.
56. MOULIN DE, FOLEY KM, EBERS GC: Pain in multiple sclerosis (MS). *Canadian Journal of Neurological Sciences*, Vol. 13, [2]:168-169, 1986.
57. FISHMAN B, PASTERNAK S, HOLLAND J, FOLEY KM: Psychological distress and coping in acute exacerbation of cancer pain. *Amer. Pain Soc.*, 77, 1986.
58. FOLEY KM, INTURRISI CE, MOULIN CE: An enkephalin analogue in pain control: analgesic efficacy and cerebrospinal fluid pharmacokinetics of DADL Enkephalin in patients with cancer pain. III World Congress on Clin Pharm & Thera, 260, 1986.
59. INTURRISI CE, WEINBERG DC, NIP TJ, WALLENSTEIN SL, HOUE RW, FOLEY KM: Sublingual absorption of opioid analgesics. *Amer. Pain Soc.*, 78, 1986.
60. PAYNE R, FOLEY KM: Exploration of the brachial plexus in patients with cancer. *Neurology*, 36:329, 1986.
61. INTURRISI CE, PORTENOY RK, MAX MB, COLBURN W, FOLEY KM: Methadone infusions: pharmacokinetic-pharmacodynamic (PK-PD) relationships. *Clin Pharma & Thera*, 211, 1986.
62. KROL G, KORI S, DECK H, FOLEY KM: Evaluation of brachial plexus by computed tomography. *Am. J. Neuroradiol.* 1:123, 1980.
63. FOLEY KM: Cancer Pain Syndromes. 14th International Cancer Congress, Budapest, Hungary, UICC, Panel Discussion: Pain Control, 4301, 1986.
64. FISHMAN B, HOUE RW, WALLENSTEIN S, FOLEY KM: Appraisal of pain relief mediates the relationship between pain intensity and emotional distress in cancer pain. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S415, 1987.
65. INTURRISI CE, PORTENOY R, MAX M, COLBURN W, FOLEY K: Pharmacokinetic-Pharmacodynamic (PK-PD) relationships of methadone and hydromorphone infusions in pain patients. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S232, 1987.
66. STILLMAN MJ, MOULIN DE, FOLEY KM: Paradoxical pain following high-dose spinal morphine. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S389, 1987.
67. MAUSKOP A, COYLE N, FOLEY KM: Continuous subcutaneous infusions (CSCI) of narcotic analgesics (NA) in cancer patients with pain. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S342, 1987.

68. COYLE N, ADELHARDT J, FOLEY KM: Changing patterns in pain, drug use and routes of administration in the advanced cancer patient. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S339, 1987.
69. FOLEY KM: The international cancer pain problem. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S210, 1987.
70. JAIN S, FOLEY KM, THOMAS J, ROONEY E: Factors influencing efficacy of epidural neurolysis therapy for intractable cancer pain. *Pain*, (Suppl 4), Fifth World Congress on Pain, IASP, S134, 1987.
71. MACALUSO C, FOLEY KM: Cordotomy for lumbosacral, pelvic, and lower extremity pain of malignant origin: safety and efficacy. *Neurology*, 38:110, 1988.
72. SALTZBURG O, GREENSLADE R, LAPIN J, FOLEY KM, INTURRISI CE: Blood profiles of heroin (H) and metabolites during repeated oral administration in cancer pain patients. *Amer. Soc. Clin. Onc.*, S73:27B, 1988.
73. ADELHARDT J, COYLE N, FOLEY KM: Subcutaneous opioid infusions in advanced cancer patients. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:S9, 1988.
74. BARKAS G, KEAVENEY ME, FOLEY KM, PORTENOY RK: Prescribing and consumption patterns of analgesic and adjuvant drugs in a major tertiary cancer center. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:S62, 1988.
75. COYLE N, ADELHARDT J, FOLEY KM: Disease progression and tolerance in the cancer pain patient. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:S58, 1988.
76. FISHMAN B, ARCURI M, WEISS J, SCIMONE L, LAPIN J, FOLEY KM: The Memorial Pain Assessment Card: Reliability and Validity For Cancer Pain. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:S52, 1988.
77. INTURRISI CE, PORTENOY RK, MAX MB, STILLMAN MJ, COLBURN W, FOLEY KM: Pharmacokinetic-pharmacodynamic (PK-PD) relationships of methadone and hydromorphone infusions in pain patients. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:S15, 1988.
78. INTURRISI CE, PORTENOY RK, STILLMAN MJ, COLBURN W, FOLEY KM: Hydromorphone bioavailability and pharmacokinetic-pharmacodynamic (PK-PD) relationships. *Amer. Soc. Clin. Pharm. Therapeu.*, March, 1988.
79. MACALUSO C, WEINBERG O, FOLEY KM: Opioid abuse and misuse in a cancer pain population. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:S54, 1988.
80. MACALUSO C, FOLEY KM: Cordotomy for lumbosacral, pelvic, and lower extremity pain of malignant origin: safety and efficacy. *Neurology*, 38:110, 1988.

81. SALTZBURG D, INTURRISI CE, GREENSLADE R, LAPIN J, NIP T, FOLEY KM: Bioavailability of heroin in cancer patients after repeated oral dosing. *J Pain Symp Manag*, Second International Congress on Cancer Pain, 3:534, 1988.
82. SALTZBURG O, GREENSLADE R, LAPIN J, FOLEY KM, INTURRISI CE: Blood profiles of heroin (H) and metabolites during repeated oral administration in cancer pain patients. *Amer. Soc. Clin. Onc.*, 573:278, 1988.
83. STILLMAN MJ, MOULIN OE, FOLEY KM: Paradoxical pain following high-dose spinal opioids. *Neurology*, 38:112, 1988.
84. STILLMAN MJ, PAYNE R, HEIER L, FOLEY KM: Perineal pain syndromes in cancer patients. *Neurology*, 38:212, 1988.
85. MACALUSO C, ARBIT E, FOLEY KM: Percutaneous cordotomy for cancer-related back, pelvic, and lower extremity pain. *Amer. Pain Soc./Can. Pain Soc.*, P-131, 1988.
86. SALTZBURG D, INTURRISI CE, NIP T, GREENSLADE R, LAPIN J, FOLEY KM: Bioavailability of heroin in cancer patients after repeated oral dosing. *Amer. Pain Soc./Can. Pain Soc.*, P-132, 1988.
87. ADELHARDT J, COYLE N, FOLEY KM: Subcutaneous opioid infusions in advanced cancer patients. *Amer. Pain Soc./Can. Pain Soc.*, SS-1-d, 1988.
88. FISHMAN 8, COPHOUS C, FOLEY KM: Cognitive aspects of disability in chronic pain. *Amer. Pain Soc./Can. Pain Soc.*, SS-6e, 1988.
89. COYLE N, ADELHARDT J, FOLEY KM: Disease progression and tolerance in the cancer pain patient. *Amer. Pain Soc./Can. Pain Soc.*, P-134, 1988.
90. SALTZBURG D, BREITBART W, FISHMAN, 8, STIEFEL F, HOLLANO J, FOLEY KM: The relationship of pain and depression to suicidal ideation in cancer patients. *Amer. Soc. Clin. Onc.*, 1989.
91. HAGEN N, STULMAN J, KROL G, FOLEY KM, PORTENOY RK: Epidural disease (ED) in cancer patients: correlation of clinical and imaging findings. *Amer. Soc. Clin. Onc.*, 1988.
92. HAGEN N, STULMAN J, KROL G, FOLEY KM, PORTENOY RK: The role of myelography and magnetic resonance imaging in cancer patients with symptomatic and asymptomatic epidural disease. *AAN*, 1989.

BIBLIOGRAPHY

1. FOLEY KM, DANES BS, BEARN AG: White blood cell cultures in genetic studies on the human mucopolysaccharidoses. *Science*, 164: 424, 1969.
2. DANES BS, FOLEY KM, DILLON SD, BEARN AG: Genetic study of cystic fibrosis of the pancreas using white blood cell cultures. *Nature*, 22: 685, 1969.
3. FOLEY KM, BERESFORD HR: Acute poliomyelitis beginning as transverse myelitis. *Arch. Neurol.* 30: 182-183, 1974.
4. FOLEY KM, POSNER JB: Does pseudotumor cerebri cause the empty sella syndrome? *Neurology* 25: 565-569, 1975.
5. FOLEY KM, POSNER JB: Pain. IN: American Academy of Neurology Review Book, Chap. 9: 199-217, 1976.
6. FOLEY KM: Neurologic Diagnostic Procedures. IN: Textbook of Medicine, Eds. PB BEESON & WF MCDERMOTT. WB Saunders, Philadelphia, 746-750, 1979.
7. VOLPE B, FOLEY KM, HOWIESON J: Normal CAT scans in craniopharyngioma. *Ann. Neurol.* 3: B7-B9, 1978.
8. SCHORR J, FOLEY KM, RUBENSTEIN M, SPECTOR S: Presence of a non-peptide morphine-like compound in human cerebrospinal fluid. *Life Sci.* 23: 2057-2062, 1978.
9. FOLEY KM: Pain Syndromes in Patients with Cancer. IN: Advances in Pain Research and Therapy, Vol. 2, Eds. JJ BONICA & V VENTAFRIDA. Raven Press, New York, 59-75, 1979.
10. FOLEY KM: The management of cancer pain. *Dallas Med. J.* 64: 517-519, 1978.
11. FOLEY KM: The management of pain of malignant origin. IN: Current Neurology, Vol. 2, Chap. 18, Eds. HR TYLER & DM DAWSON. Houghton Mifflin, Boston, 279-302, 1979.
12. FOLEY KM, WOODRUFF J, ELLIS F, POSNER JB: Radiation-induced malignant and atypical peripheral nerve sheath tumors. *Ann. Neurol.* 7: 311-318, 1980.
13. FOLEY KM, KOURIDES IA, INTURRISI CE, KAIKO RF, ZAROULIS CG, POSNER JB, HOUE RW, LI CH: B-Endorphin: Analgesic and hormonal effects in humans. *Proc. Nat. Acad. Sci. USA* 76: 5377-5381, 1979.
14. KAIKO RF, HOUE RW, ROGERS A, INTURISSI CE, WALLENSTEIN SL, GRABINSKI S, FOLEY KM: Annual Report of MSKCC Analgesic Studies Section: Disposition and Action of Narcotic Analgesics. Proceedings of the 40th Annual Scientific Meeting of the Committee on Problems of Drug Dependence, 194-216, 1978.

15. KAIKO RF, FOLEY KM, HOUOE RW, INTURRISI CE: Narcotic Levels in Cerebrospinal Fluid and Plasma in Man. IN: Characteristics and Function of Opioids, Eds. JM VAN REE & L TERENIUS. Elsevier/North-Holland Biomedical Press, Amsterdam, 221-222, 1978.
16. FOLEY KM, INTURRISI CE, KOURIDES IA, KAIKO RF, POSNER JB, HOUOE RW, LI CH: Intravenous (IV) and Intraventricular (IVT) Administration of Beta Endorphin (8zh-EP) in Man: Safety and Disposition. IN: Characteristics and Function of Opioids, Eds. JM VAN REE & L TERENIUS. Elsevier/North-Holland Biomedical Press, Amsterdam, 421-422, 1978.
17. SPECTOR S, SCHORR J, FINBERG J, FOLEY KM: Presence of a Non-Peptide Morphine-Like Compound in Human CSF and Urine. IN: Endorphins in Mental Health Research, Eds. E USOIN et al. Macmillan, London, 569-575, 1979.
18. ROTTENBERG OA, FOLEY KM, POSNER JB: Hypothesis: the pathogenesis of pseudotumor cerebri. Medical Hypotheses, 6: 913, 1980.
19. FOLEY KM: Analgesic Management of Bone Pain. IN: Bone Metastases, Eds. L WEISS & HA GILBERT. Metastases Monograph Series, Vol. 3, Chap. 4. GK Hall, Boston, 348-368, 1981.
20. KORI SH, KROL G, FOLEY KM: Computed Tomographic Evaluation of Bone and Soft Tissue Metastases. IN: Bone Metastases, Eds. L WEISS & HA GILBERT. Metastases Monograph Series, Vol. 3, Chap.10: 245-257, 1981.
21. KANNER RM, FOLEY KM: Patterns of Narcotic Drug Use in a Cancer Pain Clinic. IN: Research Developments in Drug and Alcohol Use, Ann. N.Y. Acad. Sci. 362: 161-172, 1981.
22. OIXON R, CREWS T, MOHACSI C, INTURRISI CE, FOLEY KM: Levorphanol: radioimmunoassay and plasma concentration profiles in dog and man. Res. Comm. Chem. Path. & Pharm. 29: 535-548, 1980.
23. FOLEY KM, INTURRISI CE: Intrathecal beta-endorphin (Letter to the Editor). The Lancet 199: 31, 1980.
24. FOLEY KM: The Clinical Use of Analgesics. IN: Clinical Psychopharmacology, Ed L OEROGATIS. Addison Wesley, New York, pp. 269-290, 1985.
25. FOLEY KM: Clinical assessment of pain. Acta Anesth.Scand. Supp.74:91-96, 1982.
26. KORI SH, FOLEY KM, POSNER JB: Brachial plexus lesions in patients with cancer: clinical findings in 100 cases. Neurology 31: 45-50, 1981.
27. FOLEY KM: Current Controversies in the Management of Cancer Pain. IN: NIOA Research Monograph Series, 36: 169-181, 1981.
28. OIXON R, CREWS EM, MOHACSI E, INTURRISI C, FOLEY K: Levorphanol: A simplified radioimmunoassay for clinical use. Res. Comm. Chem. Path. & Pharm. 32: 545-548, 1981.

29. KANNER RM, MARTINI N, FOLEY KM: Epidural spinal cord compression (ESCC) in pancoast (superior pulmonary sulcus) tumor: clinical presentation and outcome. *Trans. Amer. Neurol. Assoc.* 106: 75-77, 1981.
30. KANNER RM, MARTINI N, FOLEY KM: Incidence of Pain and Other Clinical Manifestations of Superior Pulmonary Sulcus Tumor (Pancoast's tumors). IN: *Advances in Pain Research and Therapy*, Vol. 4, Eds. JJ BONICA and V VENTAFRIOOA, Raven Press, New York, 27-38, 1982.
31. FOLEY KM: Neurologic Diagnostic Procedures. IN: *Textbook of Medicine*, Eds. PB BEESON & WF McOERMOTT. WB Saunders, Philadelphia, 1973-1978, 1982.
32. KAIKO RF, FOLEY KM, GRABINSKI P, HEIDRICH G, ROGERS A, INTURRISI CE, REIDENBERG M: Central nervous system excitatory effects of meperidine in cancer patients. *Ann. Neurol.* 13: 180-185, 1983.
33. INTURRISI CE, ALEXOPOULOS G, LIPMAN R, FOLEY KM, ROSSIER J: Beta-Endorphin Immunoreactivity in the Plasma of Psychiatric Patients Receiving Electro-Convulsive Treatment. IN: *Opioids in Mental Illness*, Ann. N.Y. Acad. Sci., 398: 413-423, 1983.
34. GRABINSKI PY, KAIKO RF, WALSH TO, FOLEY KM: Morphine radioimmunoassay specificity before and after extraction of plasma and cerebrospinal fluid. *J. Pharm. Sci.*, 72: 27-29, 1983.
35. FOLEY KM: The Management of Cancer Pain, Vol. I. Pain Syndromes in Patients With Cancer. Hoffmann-LaRoche Monograph Series, 1982.
36. FOLEY KM, ROGERS A: The Management of Cancer Pain, Vol. II. The Rational Use of Analgesics in the Management of Cancer Pain. Hoffmann-LaRoche Monograph Series, 1982.
37. CASCINO TL, KORI S, KROL G, FOLEY KM: CT scanning of the brachial plexus in patients with cancer. *Neurology* 33: 1553-1557, 1983.
38. FOLEY KM: The Practical Use of Narcotic Analgesics. IN: *The Medical Clinics of North America*, 1091-1104. Ed. MM REIDENBERG. WB Saunders, Philadelphia, 1982.
39. MAX MB, INTURRISI CE, KAIKO RF, GRABINSKI PY, LI CH, FOLEY KM: Epidural and intrathecal opiates: distribution in CSF and plasma and analgesic effects in patients with cancer. *Clin. Pharm. Ther.*, 38:631-641, 1985.
40. FOLEY, KM: The control of pain in cancer. IN: *Medical Oncology: Basic Principles and Clinical Management of Cancer*. Eds. P CALABRISI, P SCHEIN, S ROSENBERG. Macmillan Co, New York, 1385-1405, 1985.
41. INTURRISI CE, MAX M, FOLEY KM, SCHULTZ M, SEUNG-UON S, HOUOE R: The pharmacokinetics of heroin in patients with chronic pain. *N. Eng. J. Med.*: 310: 1213-1217, 1984.

42. INTURRISI CI, FOLEY KM: Narcotic Analgesics in the Management of Pain. IN: Analgesics: Neurochemical Behavioral and Chemical Perspectives, Eds. M KUHAR, GW PASTERNAK. Raven Press, New York, 257-288, 1983.
43. DIXON R, CREWS T, INTURRISI CE, FOLEY KM: Levorphanol: pharmacokinetics and steady-state plasma concentrations in patients with pain. Res. Comm. Chem. Path. & Pharm. Vol. 41: 3-17, 1983.
44. FOLEY, KM: Assessment of Pain. IN: Clinics in Oncology. Ed. R TWYLCROSS. WB Saunders, London, England, 17-32, 1983.
45. FOLEY, KM: Adjuvant analgesic drugs in the management of cancer pain. Mediguide to Pain. Lawrence DellaCorte Publications, New York, Vol. 4: 1-8, 1983.
46. FOLEY, KM: Management of Pain in the Cancer Patient. IN: Supportive Care of the Cancer Patient. Biomedical Information Corp., New York, 28-35, 1983.
47. FOLEY, KM: Adjuvant Analgesic Drugs in the Management of Cancer Pain. IN: Relief of Chronic Pain. Ed. GM ARONOFF. Addison Wesley Pubs., Mass., 425-434, 1983.
48. JAECKLE KA, YOUNG OF, FOLEY KM: The natural history of lumbosacral plexopathy in cancer. Neurology, 35: 8-14, 1984.
49. PAYNE R, FOLEY KM: Advances in the management of cancer pain. Cancer Treat. Rep. 68:173-183, 1984.
50. FOLEY KM: Cancer Pain. IN: Current Therapy in Neurologic Disease. Ed. RT JOHNSON: B.C. Decker, Inc., Philadelphia, 61-68, 1984.
51. FOLEY KM, SUNDARESAN N: The Management of Cancer Pain. IN: Cancer Principles & Practice of Oncology. Eds. VT DEVITA, S HELLMAN, SA ROSENBERG. J. Lippincott, New York, 1940-1962, 1985.
52. MOULIN DE, FOLEY KM: Management of pain in patients with cancer. Psych. Ann., 14:815-822, 1984.
53. FOLEY KM: The Management of Cancer Pain. IN: Current Therapy in Internal Medicine. Eds. TM BAYLESS, MC BRAIN, RM CHERNIACK. B.C. Decker, Inc., Philadelphia, 1288-1294, 1984.
54. FOLEY KM: A Review of Pain Syndromes in Patients with Cancer. IN: The Management of Cancer Pain. Eds. Hospital Practice: 7-16, 1984.
55. FOLEY KM: Pharmacological Approaches to Pain Control. IN: New Developments In Pain Research and Treatment. Ed. HL BERKOWITZ, Amer. Psych. Press, Washington, 35-48, 1984).
56. FOLEY KM: The treatment of cancer pain. N. Eng. J. Med. 313:84-95, 1985.

57. PORTENOY RK, FOLEY KM: Clinical and pharmacological considerations in the use of narcotic analgesics in the elderly. *Geriatric Medicine Today* 4:32-37, 1985.
58. COYLE N, MONZILLO E, LOSCALZO M, FARKAS C, MASSIE MJ, FOLEY KM: A model of continuity of care for cancer patients with pain and neuro-oncologic complications. *Cancer Nursing*, 8:111-119, 1984.
59. SUNOARESAN N, SHAH J, FOLEY KM, ROSEN G: An anterior surgical approach to the upper thoracic vertebrae. *J Neurosurg*, 61:686-690, 1984.
60. CHAPMAN CR, CASEY KL, OUBNER R, FOLEY KM, GRACEY RH, READING AE: Pain measurement: an overview. *Pain*, 2:1-32, 1985.
61. COYLE N, FOLEY KM: Pain in patients with cancer: profile of patients and common pain syndromes. *Seminar in Oncology Nursing* 1:93-99, 1984.
62. MOULIN O, MAX M, KAIKO RF, INTURRISI CE, MAGGARD J, YAKSH T, FOLEY KM: The analgesic efficacy of intrathecal O-Ala²-O-Leu⁵-Enkephalin in cancer patient with chronic pain. *Pain*, 23:213-221, 1985.
63. PORTENOY R, FOLEY KM: The Management of Cancer Pain. IN: *Handbook of Psychologic Oncology*, Eds. HOLLAND J, ROLAND L., Oxford Press, New York, In press, 1988).
64. FOLEY KM: Current Controversies in Opioid Therapy. IN: *Advances in Pain Research and Therapy: Opioid Analgesics in the Management of Clinical Pain*. Eds. FOLEY KM, INTURRISI CE, Raven Press, New York, 3-11, 1986.
65. FOLEY KM: Analgesic and Hormonal Effects of B-endorphin. IN: *Advances in Pain Research and Therapy: Opioid Analgesics in the Management of Clinical Pain*. Eds. FOLEY KM, INTURRISI CE, Raven Press, New York, 285-292, 1986.
66. MOULIN OE, INTURRISI CE, FOLEY KM: Epidural and intrathecal opioids: cerebrospinal fluid and plasma pharmacokinetics in cancer pain patients. IN: *Advances in Pain Research and Therapy*, Vol. 8: *Opioid Analgesics in the Management of Clinical Pain*. Eds. FOLEY KM, INTURRISI CE, Raven Press, New York, 369-384, 1986.
67. PORTENOY RK, MOULIN DE, ROGERS A, INTURRISI CE, FOLEY KM: Intravenous Infusions of Opiates in Cancer Pain: Review of Cases and Guidelines for Use. IN: *Advances in Pain Research and Therapy*, Vol. 8: *Opioid Analgesics in the Management of Clinical Pain*. Eds. FOLEY KM, INTURRISI CE, Raven Press, New York, 413-424, 1986.
68. FOLEY KM: Commentary on Heroin: Facts and Comparisons. *PRN Forum*, 1:2, 1985.

69. FOLEY KM: Pharmacologic approaches to cancer pain management. IN: *Advances in Pain Research and Therapy. Pain (Suppl 2)*, Fourth World Congress on Pain, IASP, Ed. FIELDS H, Raven Press, New York, 629-653, 1985.
70. GLASS JP, FOLEY KM: Harmful effects of radiation. IN: *Diseases of the Nervous System*. Eds. ASBURY AK, MCKHANN GM, McDONALD WI, WB Saunders Company, Philadelphia, 1188-1202, 1986.
71. PORTENOY RK, LIPTON RB, FOLEY KM: Back Pain in the Cancer Patient: An algorithm for evaluation and management. *Neurology*, 37,134-138, 1986.
72. PORTENOY RK, FOLEY KM: Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. *Pain*, 25:171-186, 1986.
73. FOLEY KM: Cancer and Pain. IN: *The American Cancer Society Cancer Book*. Ed. HOLLEB A, Doubleday & Co., New York, 225-237, 1986.
74. MOULIN DE, INTURRISI CE, FOLEY KM: Cerebrospinal fluid pharmacokinetics of intrathecal morphine sulfate and D-Ala²-D-Leu⁵- Enkephalin. *Ann. Neuro.*, 20: 218-222, 1986.
75. PORTENOY RK, MOULIN DE, ROGERS A, INTURRISI CE, FOLEY KM: Intravenous infusion of opioids in cancer pain: clinical review and guidelines for use. *Ca Treat Rep*, 70:575-581, 1985.
76. GRAUS F, KROL G, FOLEY KM: Early diagnosis of spinal epidural metastasis (SEM): Correlation with clinical and radiological findings. (*J. Clin. Oncol.*, In Press, 1987).
77. MOULIN DE, FOLEY KM: Drug management of cancer pain. (Letter), *Canadian Medical Association Journal*, 546, 1985.
78. PORTENOY RK, DUMA C, FOLEY KM: Acute herpetic and postherpetic neuralgia: clinical review and current management. *Ann. Neurol.*, 20:651-664, 1987.
79. INTURRISI CE, FOLEY KM, MAX M, CHEN J, SCHULTZ M, HOUE R: Disposition and effects of heroin in pain patients. *Clin. J. Pain*, 1:111-115, 1985.
80. PORTENOY RK, FOLEY KM: Pain. IN: *Merck Manual*. Merck, Sharp & Dohme, New York, 1340-1351, 1987.
81. FOLEY KM. Brachial plexopathy in patients with breast cancer. Eds. JR HARRIS, S HELLMAN, IC HENDERSON, D KINNE. IN: *Breast Diseases*. JP Lippincott, Philadelphia, 532-537, 1987.
82. STILLMAN M, FOLEY KM: Diagnosis and treatment of pain in breast cancer. Eds. JR HARRIS, S HELLMAN, IC HENDERSON, D KINNE. IN: *Breast Diseases*. JP Lippincott, Philadelphia, 683-696, 1987.
83. GLASS JP, FOLEY KM: Brain metastases in breast cancer. Eds. JR HARRIS, S HELLMAN, IC HENDERSON, D KINNE. IN: *Breast Diseases*. JP Lippincott, Philadelphia, 480-487, 1987.

84. GLASS PJ, FOLEY KM: Carcinomatous meningitis. Eds. JR HARRIS, S HELLMAN, IC HENDERSON, D KINNE. IN: Breast Diseases. JP Lippincott, Philadelphia, 497-505, 1986.
85. PAYNE R, FOLEY KM, INTURRISI CE: CSF pharmacokinetics of opiates in a sheep model. IN: Advances in Pain Research and Therapy, Vol. 8: Opioid Analgesics in the Management of Clinical Pain. Eds. KM FOLEY, CE INTURRISI, Raven Press, New York, 385-390, 1986.
86. PORTENOY RK, JARDEN JO, SIDTIS JJ, LIPTON RB, FOLEY KM, ROTTENBERG DA: Compulsive thalamic self-stimulation: a case with metabolic, electrophysiologic and behavioral correlates. Pain, 277-290, 1986.
87. INTURRISI CE, FOLEY KM, MAX MB, CHEN J, SCHULTZ M, HOUE RW: Disposition and effects of heroin in pain patients. IN: Advances in Pain Research and Therapy, Vol. 9. Eds. H.L. FIELDS, Raven Press, New York, 709-718, 1985.
88. FOLEY KM: The treatment of pain in the patients with cancer. IN: CA-A Cancer Journal for Clinicians, American Cancer Society, 4:194-215, 1986.
89. COYLE N, MAUSKOP A, MAGGARD J, FOLEY KM: Continuous subcutaneous infusions of opiates in cancer patients with pain. Onc Nurs Forum 4:53-57, 1986.
90. MAUSKOP A, FOLEY KM: Control of pain. IN: HARRINGTON, K (Ed.), Orthopaedic Management of Metastatic Bone Disease, Mosby Publishers, St. Louis, Mo. pp. 121-140, 1988.
91. STILLMAN M, FOLEY KM: Breast cancer and epidural spinal cord compression: Diagnostic and therapeutic strategies. Eds. JR HARRIS, S HELLMAN, IC HENDERSON, D KINNE. IN: Breast Diseases. JP Lippincott, Philadelphia, 488-497, 1987.
92. FISHMAN B, PASTERNAK S, WALLENSTEIN SL, HOUE R, HOLLAND JC, FOLEY KM: The Memorial Pain Assessment Card: A Valid Instrument for the Evaluation of Cancer Pain. Cancer, 60:1151-1158, 1987.
93. FOLEY KM: Assessment of pain in patient with cancer. IN: Swerdlow M, Ventafridda V (Eds.), Cancer Pain. MTP Press Limited, England, 37-44, 1987.
94. FOLEY KM: Pain syndromes in patients with cancer. IN: Swerdlow M, Ventafridda V (Eds.), Cancer Pain. MTP Press Limited, England, 45-56, 1987.
95. FOLEY KM, POSNER JB: Pain. In: Cecil's Textbook of Medicine, 18th ed. JB Wyngaarten, LH Smith Jr. (Eds). WB Saunders, Philadelphia, ? 1987.
96. FADUL C, FOLEY KM: Tratamiento del dolor por cancer. Eighth Argentine Congress on Pain, In Press, 1988.

97. KAIKO RF, KANNER R, FOLEY KM, WALLENSTEIN SL, CANEL AM, ROGERS AG, HOUDE RW: Cocaine and morphine interaction in acute and chronic cancer pain. *Pain*, 31:35-46, 1987.
98. FOLEY KM: Pain syndromes in patients with cancer. IN: FOLEY KM, PAYNE R (Eds.), *Medical Clinics in North America*, Vol. 71, No. 2, W.B. Saunders, Philadelphia, 169-184, 1987.
99. LIPTON RB, PORTENOY RK, FOLEY KM: Back pain in cancer patients. *Emergency Decisions*, 3:33-50, 1987.
100. COYLE N, FOLEY KM: Prevalence and Profile of Pain Syndromes in Cancer Patients. IN: MCGUIRE DB, YARBRO CH (Eds.). *Cancer Pain Management*. Grune and Stratton Inc., Florida, 21-46, 1986.
101. FOLEY KM, INTURRISI CE: Analgesic drug therapy in cancer pain: principles and practice. IN: PAYNE R, FOLEY KM (Eds.). *Medical Clinics of North America*, Vol. 71, No. 2, W.B. Saunders, Philadelphia, 207-232, 1987.
102. FOLEY KM, INTURRISI CE: Pharmacological management of cancer pain. IN: PAYNE R, FOLEY KM (Eds.). *Current Therapy of Pain*, 8.C. Decker, Philadelphia, In Press, 1988.
103. INTURRISI CE, COLBURN WA, KAIKO RF, HOUDE RW, FOLEY KM: Pharmacokinetic and pharmacodynamics of methadone in chronic pain patients. *Clin Pharmacology & Therapeutics*, 41:392-401, 1987.
104. FOLEY KM: Cancer pain syndromes. *J Pain Symp Mgmt*, Vol. 2, No. 2, S13-S17, 1987.
105. FADUL CE, FOLEY KM: Narcóticos en el manejo del dolor por cancer. IN: *Pain. Mexican Association for Pain*, Tijuana, Mexico, In Press, 1988.
106. PORTENOY RK, MOULIN DE, ROGERS AG, INTURRISI CE, FOLEY KM: IV infusion of opioids for cancer pain: clinical review and guidelines for use. IN: RIVERA DS (Ed) *Year Book of Cancer*, In Press, 1988.
107. PORTENOY RK, FOLEY KM: Opioids in non-malignant pain. (Letter), *Pain*, 29:259-262, 1987.
108. WEINBERG DS, INTURRISI CE, REIDENBERG B, MOULIN DE, NIP TJ, WALLENSTEIN S, HOUDE RW, FOLEY KM: Sublingual absorption of selected opioid analgesics. *Clin Pharm Therap*, 44:335-342, 1988.
109. LAPIN J, KAIKO RF, COYLE C, ROGERS AG, HOUDE RW, FOLEY KM: Cancer pain management with a controlled-release morphine. *Cancer Nursing*, In Press, 1988.
109. FOLEY KM, The treatment of cancer pain. (Letter), *New Eng J Med*, 315:6, 1986.
110. FOLEY KM. Author's Reply to Letter to the Editor. *Ca-A Cancer Journal for Clinicians*, Vol. 37, No. 6, 375-376, 1987.

111. FOLEY KM, ARBIT E: Management of cancer pain. IN: Cancer Principles & Practice of Oncology. Eds. VT DEVITA, S HELLMAN, SA ROSENBERG. J. Lippincott, New York, Second Edition, In Press, 1988.
112. FOLEY KM: The rational use of analgesics in the management of patients with acute and chronic pain. Clinical Neurosurgery 35: In Press, 1988.
113. STILLMAN HJ, CHRISTENSEN W, PAYNE R, FOLEY KM: Leukemic relapse presenting as sciatic nerve involvement by chloroma (granulocytic sarcoma). Cancer, 62:2047-2050, 1988.
114. FOLEY KM: The cancer pain patient. J Pain & Symp Manag, Vol. 3, No. 1, S16-S19, 1988.
115. MOULIN DE, FOLEY KM, EBERS G: Pain in multiple sclerosis. Neurology, In Press, 1988.
116. MACALUSO C, FOLEY KM: Managing pain in patients with lung cancer. J Resp Oiseases, 9:59-80, 1988.
117. FOLEY KM (Ed): Management of Cancer Pain, Postgraduate Course Syllabus, Memorial Sloan-Kettering Cancer Center, New York, 1985.
118. FOLEY KM, INTURRISI CE: (Eds.) Advances in Pain Research and Therapy, Vol. 8: Opioid Analgesics in the Management of Clinical Pain. Raven Press, New York, 1986.
119. PAYNE R, FOLEY KM (Eds.): Medical Clinics in North America, W.8. Saunders, Philadelphia, Vol. 71, No. 2, March, 1987.
120. PAYNE R, FOLEY KM (Eds.): Current Therapy in Pain. 8.C. Decker, Philadelphia, In Press, 1988.
121. SALTZBURG D, FOLEY KM: The management of pancreatic cancer pain. IN: REBER H (Ed) Surgical Clinics of North America, Philadelphia, W.8. Saunders, In Press, 1988.
122. FOLEY KM: The management of pain in pancreatic cancer. J Pain Symp Manag, 3:176-187, 1988.
123. FOLEY KM, VENTAFRIODA V, BONICA JJ (Eds.) Advances in Pain Research and Therapy, Proceedings of the Second International Congress on Cancer Pain, Raven Press, New York, In Press, 1988.
124. FOLEY KM: The Decriminalization of Cancer Pain: IN: Hill S (Eds.) Advances in Pain Research and Therapy--The Management of Pain in a Drug Oriented Society, Raven Press, New York, In Press, 1988.
125. FOLEY KM: Controversies in cancer pain--medical perspective. Cancer, In Press, 1988.
127. REBER HA, FOLEY KM (Eds): Pancreatic cancer pain: presentation, pathogenesis and management. J Pain Symp Manage, Vol. 3, 1988.
128. FOLEY KM: Management of cancer pain. IN: Textbook on Clinical Oncology. American Cancer Society, In Press, 1988.

UNIVERSITY OF MINNESOTA
TWIN CITIESUNIVERSITY OF MINNESOTA
TWIN CITIESDepartment of Medicinal Chemistry
College of Pharmacy
308 Harvard Street S.E.
Minneapolis, Minnesota 55455

February 3, 1989

James W. Elder
Senior Business Manager
Medicinal Narcotics
Mallinckrodt, Inc.
Mallinckrodt and Second Streets
St. Louis, MO 63147

Dear Mr. Elder:

I am responding to your letter of 25 Jan 1989 in which you requested that I address two questions relating to the importance of opium-derived substances.

Your first question, whether opium-derived compounds would provide important new therapeutic advances over drugs that are now available, is easy to answer in view of the progress made in opioid research over the past ten years. The discovery of multiple opioid receptors has opened new avenues for the development of analgesics with little abuse potential or other side effects. The first generation of these superior analgesics (nalbuphine and buprenorphine) are derived from the opium component, thebaine.

Since endogenous opioids modulate so many different physiologic processes, through multiple opioid receptors, drugs that selectively block these receptors may find important clinical application. For example, there is evidence that blocking one subpopulation (delta) of opioid receptors inhibits the appetite for alcohol in experimental animals. Thus, a selective opioid antagonist may be useful in treating alcoholism. Still another potential application is in the prevention of paralysis due to spinal trauma. In this regard, it has been found that the endogenous opioid peptide, dynorphin, reduces blood flow at the site of injury and this leads to paralysis. Indeed, it has been reported that opioid antagonists can prevent dynorphin effects and thereby prevent the paralysis. Still another example is the use of opioid antagonists in the treatment of shock. For example, the administration of an opioid antagonist (naltrexone, naloxone) reverses the life-threatening effects in the shock syndrome.

Dr. Elder
February 3, 1989
Page Two

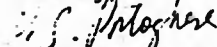
The opioid antagonists employed in the aforementioned studies are all synthesized from thebaine. Since thebaine is the sole starting material for the clinically employed opioid antagonists, naloxone and naltrexone, and in the development of highly selective opioid antagonists, it is important that the supply of this opium-derived compound be maintained.

With regard to your second question pertaining to the availability of totally synthetic compounds that could adequately replace current opium-derived drugs, I would say there are few, if any. I know of no adequate synthetic replacements for naloxone or naltrexone. Butorphanol is the only compound among the most recent generation of clinically employed mixed agonist-antagonist analgesics that has a pharmacologic profile similar to that of thebaine-derived drugs in this class. However, relying on a single analgesic in this class is unwise.

Finally, opium components serve not only as an important source of starting material for the synthesis of new opioid antagonists and new nonaddictive analgesics, but they also are crucial to researchers involved in the design of new pharmacologic tools for research purposes. Our understanding of the mechanisms of opioid dependence requires the use of highly selective molecules, many of which are derived from thebaine. A better understanding of the molecular mechanisms of opioid dependence will in turn permit the development of superior analgesics that are safe and devoid of abuse potential.

I hope this letter is of assistance in your review. If there is additional information that you require please feel free to contact me.

Sincerely,



P.S. Portoghesi, Ph.D.
Professor of Medicinal Chemistry
and Pharmacology

PSP/law

C:ELDER

ATTACHMENT III

RETYPE FROM ORIGINAL FOR CLARITY

- 2 -

STATEMENT SHOWING THE AREA LICENSED, HARVESTED, PRODUCE OF
OPIMUM AT 90°C AND AVERAGE YIELD AT 90°C FROM THE YEAR
1977-78 TO 1987-88.

Crop year	Area licensed for poppy Cultivation (in hecsts.)	Production of Opium in tones at 90°C
1.	2.	
1977-78	66338.58	1646
1978-79	53697.81	1413
1979-80	40171.61	969
1980-81	36826.49	1162
1981-82	35405.84	935
1982-83	32350.56	997
1983-84	25520.16	447
1984-85	25487.09	789
1985-86	24361.15	683
1986-87	23335.77	699
1987-88	22749.55	563

DDP.

Source: Government of India, Central Bureau of Narcotics

ATTACHMENT IV
RETYPE FROM ORIGINAL FOR CLARITY

- 6 -

STATEMENT SHOWING THE MINIMUM QUALIFYING YIELD FIXED FOR
POPPY CULTIVATION FROM THE CROP YEAR 1978-79 TO 1988-89

Crop Year	Minimum qualifying yield at 70°C. per hectare/kgs.
1978-79	25
1979-80	25
1980-81	25
1981-82	28
1982-83	28
1983-84	28
1984-85	26
1985-86	30
1986-87	32
1987-88	
1988-89	

DDP/-

Source: Government of India, Central Bureau of Narcotics

**EXTRACTS FROM THE NARCOTIC DRUGS AND PSYCHOTROPIC
SUBSTANCES RULES, 1985 RELATING TO POPPY
CULTIVATION**

CHAPTER III

**OPIUM POPPY CULTIVATION AND PRODUCTION
OF OPIUM AND POPPY STRAW**

**OPIUM POPPY
CULTIVATION
AND PRODUCTION
OF OPIUM OR
POPPY STRAW**

5. The opium poppy for production of opium or poppy straw shall not be cultivated save on account of the Central Government and in the tracts notified by it from time to time and in accordance with the conditions of a licence issued by the District Opium Officer under rule 8.

**FEE FOR
GRANT OF
LICENCE**

6. The licence for cultivation of opium poppy may be granted by the District Opium Officer on payment of a fee of rupees five.

**FORM OF
LICENCE FOR
CULTIVATION
OF THE
OPIUM POPPY**

7. The licence for cultivation of opium poppy for the production of opium or poppy straw shall be issued in Form No. 1 appended to these rules.

**ISSUE OF
LICENCE**

8. Subject to the general conditions relating to grant of licences notified by the Central Government, the District Opium Officer may issue licence to any person for a crop year for cultivation of the opium poppy for production of opium or poppy straw on receipt of an application made by that person in Form No. 2 appended to these rules.

**LICENCE TO
SPECIFY THE
AREA, ETC.**

9. The licence for cultivation of opium poppy issued under rule 8 shall specify the area and designate the plots to be cultivated with opium poppy.

**DESIGNATING
OF LAMBARDAR**

10. The District Opium Officer may designate one of the cultivators of opium poppy as Lambardar in each village where opium poppy cultivation is permitted, who shall perform such functions and on such terms and conditions as may be specified from time to time by the Narcotics Commissioner.

**WITHHOLDING
OR CANCEL-
LATION OF
LICENCE**

11. (1) An officer higher in rank than the District Opium Officer may, for sufficient reasons to be recorded in writing, withhold or cancel a licence already issued.

(2) No order shall be passed under sub-rule (1) unless the cultivator has been given a reasonable opportunity of showing cause against the said order or is heard in person, if he so desires.

(3) Where opium poppy has been cultivated under a licence which is subsequently withheld or cancelled, the standing crop, if any, shall be destroyed under the supervision of the proper officer in such manner as may be specified by the Narcotics Commissioner.

**PROCEDURE
WITH REGARD
TO MEASUREMENT
OF LAND
CULTIVATED WITH
OPIUM POPPY**

12. (1) All plots of land cultivated with opium poppy in accordance with the licence issued under these rules, shall be measured in metres by the proper officer in the presence of the cultivator concerned and the Lambardar of the village and the concerned cultivator and the Lambardar of the village shall attest the entries made in the records to be maintained by the Lambardar, as may be specified by the Narcotics Commissioner in this behalf, under their signature/thumb impression with date, in token of having satisfied themselves regarding the correctness of the measurement.

(2) The measurement conducted by the proper officer shall be subject to such further checks by such officers as may be specified by the Narcotics Commissioner in this behalf.

**PROCEDURE
WITH REGARD
TO PRELIMINARY
WEIGHMENT**

13. (1) The cultivator shall, during the course of harvesting, produce daily before the Lambardar, each day's collection of opium from his crop for weighment.

(2) The Lambardar shall make arrangements to weigh such opium and make necessary entries in the records to be maintained by him as may be specified by the Narcotics Commissioner in this behalf.

(3) The cultivator and the Lambardar shall attest the entries made in such records under their signature/thumb impression with date, showing the quantity of opium weighed on a particular day.

(4) The proper officer shall conduct check weighment of the opium collected by the cultivators with reference to the entries in the Lambardar's record and indicate his finding therein which shall be attested by him and the Lambardar under their signature with date.

(5) The variations between the quantity of opium produced by the cultivator indicated in the Lambardar's record and as found by the proper officer during his check, shall be inquired into by the proper officer in order to ascertain the liability of the cultivator for punishment under section 19 of the Act.

**DELIVERY OF
OPIUM PRODUCED**

14. All opium, the produce of land cultivated with opium poppy, shall be delivered by the cultivators to the District Opium Officer or any other officer duly authorised in this behalf, by the Narcotics Commissioner at a place as may be specified by such officer.

**OPIUM TO BE
WEIGHED,
EXAMINED AND
CLASSIFIED**

15. All opium delivered by the cultivators to the District Opium Officer or any other officer authorised as aforesaid, shall, in the presence of the concerned cultivator or any person authorised by him and the Lambardar of the village, be weighed, examined and classified according to its quality and consistence and forwarded by the District Opium Officer to the Government Opium Factory in such manner as may be specified by the Narcotics Commissioner.

FORM NO. 1
(See Rule - 7)

GOVERNMENT OF INDIA
CENTRAL BUREAU OF NARCOTICS

DIVISION _____

CROP SEASON FOR
WHICH VALID _____

LICENCE TO GROW OPIUM POPPY FOR PRODUCTION OF OPIUM OF POPPY STRAW

Name and Parentage of the Licensee Village Pergana/District Licence Number Area licensed Plot No. (s) as per revenue records.

	Hectares	Area	Signature
Area measured (S.I.).
Area test-measured (Inspector/ D.O.O.)
Area harvested (S.I.)

Signature & Seal
District Opium Officer.

Plate No.	Class of opium as assigned by D.O.O. (kg).	(Entries to be made at the time of weight of weightments)				Entries to be made at the time of final payment.			
		Price payable on the basis of final assumed weight 70°C	Amount withheld pending final examination of opium at factory	Amount paid at weight of opium at 70°C on the basis of factory's report.	Total weight of opium at 70°C on the basis of factory's report.	Average yield of opium at cut-vator.	Total amount already paid at the time of final payments	Amount recovered at the time of final payments	Amount paid/ recovered at the time of final payments
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
									11.
									12.

Signature & Seal (D.O.O.)

Signature & Seal (D.O.O.)

Conditions of the Licence

1. The licensee shall not transfer this licence and cultivate poppy only for production of opium or poppy straw over the area of land and the Plot(s) specified in the licence.
2. The land in which poppy will be cultivated by the cultivator shall be free from litigation.
3. The licensee shall get his daily collections of opium obtained from the crop weighed by the Lambardar and affix his signature/thumb impression against each entry made by the Lambardar in token of correctness of such entry made by the Lambardar shall submit to preliminary weighments carried out by the staff of the Narcotics Department in the village during which he shall produce the entire quantity collected by him.
4. The licensee shall bring to, and deliver at, the place fixed and notified for weighments, all opium collected by him from the crop and shall accept for opium so brought by him the price fixed by the Central Government for that crop year.
5. The licensee shall deliver the opium either himself or through any person authorised by him at the time of its weighments and his opium shall be weighed under the supervision of the District Opium Officer or any other officer authorised in this behalf by the Narcotics Commissioner in accordance with Rule 15 of the Narcotic Drugs and Psychotropic Substances Rules, 1985.
6. If the licensee does not surrender his entire produce of opium to Government or retains, embezzles or otherwise illegally disposes of any part of the same, he shall be liable to be prosecuted as per the provisions of the Narcotic Drugs and Psychotropic Substance Act, 1985.
7. The licensee shall extract as much opium as is reasonably possible from all implements, pots and cloth used by him in collecting opium and impregnated with opium is consequence of such use.
8. The final payment for opium delivered by the licensee shall be made to him at appropriate time fixed by the District Opium Officer or any other officer authorised in this behalf.
9. If on the final adjustment of accounts any sum is found due from the licensee, he shall pay it to the District Opium Officer or any other officer authorised in this behalf in the manner specified. If the licensee fails to pay the sum due from him, it may be recovered from him in the manner prescribed by section 72 of the Narcotic Drugs and Psychotropic Substances Act, 1985.
10. The licence may be withheld or cancelled at any time if any fact is revealed against the licensee which makes him ineligible for grant of the licence.
11. The licensee shall comply with the provisions of Narcotic Drugs and Psychotropic Substances Act, 1985, the Rules framed thereunder and any order issued by the competent authorities of the Narcotics Department from time to time.
12. The licensee shall be punishable under the relevant provisions of the Narcotic Drugs and Psychotropic Substances Act, 1985 for any breach of the conditions of this licence.

रीकॉर्ड नं. डी(जेन)127/88

REGISTERED No. D(DN)127/88



भारत का राजपत्र The Gazette of India

असाधारण
EXTRAORDINARY

भाग II—खण्ड 1
PART II—Section 1

प्रतिपक्षार से प्रकाशित
PUBLISHED BY AUTHORITY

नं० 60] नई दिल्ली, बृहस्पति, सितम्बर 6, 1988/भाद्र 15, 1910
No. 60] NEW DELHI, TUESDAY, SEPTEMBER 6, 1988/BHADRA 15, 1910

इस भाग में निम्न एक संख्या दी जाती है जिसमें कि वह कथन संकलन
के रूप में रखा जा सके।

Separate paging is given to this Part in order that it may be filed
as a separate compilation

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the 6th September, 1988/Bhadra 15, 1910 (Saka)

The following Act of Parliament received the assent of the President on the 6th September, 1988, and is hereby published for general information:—

THE PREVENTION OF ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, 1988

No. 46 of 1988.

[6th September, 1988.]

An Act to provide for detention in certain cases for the purpose of preventing illicit traffic in narcotic drugs and psychotropic substances and for matters connected therewith.

WHEREAS illicit traffic in narcotic drugs and psychotropic substances poses a serious threat to the health and welfare of the people and the activities of persons engaged in such illicit traffic have a deleterious effect on the national economy;

AND WHEREAS having regard to the persons by whom and the manner in which such activities are organised and carried on, and having regard to the fact that in certain areas which are highly vulnerable to the illicit traffic in narcotic drugs and psychotropic substances, such activities of a considerable magnitude are clandestinely organised and carried on, it is necessary for the effective prevention of such activities to provide for detention of persons concerned in any manner therewith.

(1)

Be it enacted by Parliament in the Thirty-ninth Year of the Republic of India as follows:—

Short
title,
extent
and
commen-
cement.

1. (1) This Act may be called the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988.

(2) It extends to the whole of India except the State of Jammu and Kashmir.

(3) It shall be deemed to have come into force on the 4th day of July, 1988.

Defini-
tions.

2. In this Act, unless the context otherwise requires,—

(a) "appropriate Government" means, as respects a detention order made by the Central Government or by an officer of the Central Government, or a person detained under such order, the Central Government, and as respects a detention order made by a State Government or by an officer of a State Government, or a person detained under such order, the State Government;

(b) "customs airport" means any airport appointed under clause (a) of section 7 of the Customs Act, 1962 to be a customs airport;

32 of 1962.

(c) "detention order" means an order made under section 3;

(d) "foreigner" has the same meaning as in the Foreigners Act, 1946;

31 of 1946.

(e) "illicit traffic", in relation to narcotic drugs and psychotropic substances, means—

(i) cultivating any coca plant or gathering any portion of coca plant;

(ii) cultivating the opium poppy or any cannabis plant;

(iii) engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use or consumption, import inter-State, export inter-State, import into India, export from India or transshipment, of narcotic drugs or psychotropic substances;

(iv) dealing in any activities in narcotic drugs or psychotropic substances other than those provided in sub-clauses (i) to (iii); or

(v) handling or letting any premises for the carrying on of any of the activities referred to in sub-clauses (i) to (iv),

other than those permitted under the Narcotic Drugs and Psychotropic Substances Act, 1985, or any rule or order made, or any condition of any licence, term or authorisation issued, thereunder and includes—

61 of 1985.

(1) financing, directly or indirectly, any of the aforementioned activities;

(2) abetting or conspiring in the furtherance of or in support of doing any of the aforementioned activities; and

(3) harbouring persons engaged in any of the aforementioned activities;

52 of 1962.

(f) "Indian customs waters" has the same meaning as in clause (28) of section 2 of the Customs Act, 1962;

(g) "State Government", in relation to a Union territory, means the Administrator thereof;

61 of 1985.

(h) words and expressions used herein but not defined, and defined in the Narcotic Drugs and Psychotropic Substances Act, 1985, have the meanings respectively assigned to them in that Act.

3. (1) The Central Government or a State Government, or any officer of the Central Government, not below the rank of a Joint Secretary to that Government, specially empowered for the purposes of this section by that Government, or any officer of a State Government, not below the rank of a Secretary to that Government, specially empowered for the purposes of this section by that Government may, if satisfied, with respect to any person (including a foreigner) that, with a view to preventing him from engaging in illicit traffic in narcotic drugs and psychotropic substances, it is necessary so to do, make an order directing that such person be detained.

Power to make orders detaining certain persons.

(2) When any order of detention is made by a State Government or by an officer empowered by a State Government, the State Government shall, within ten days, forward to the Central Government a report in respect of the order.

(3) For the purposes of clause (5) of article 22 of the Constitution, the communication to a person detained in pursuance of a detention order of the grounds on which the order has been made shall be made as soon as may be after the detention, but ordinarily not later than five days, and in exceptional circumstances and for reasons to be recorded in writing, not later than fifteen days, from the date of detention.

2 of 1974.

4. A detention order may be executed at any place in India in the manner provided for the execution of warrants of arrest under the Code of Criminal Procedure, 1973.

Execution of detention orders.

5. Every person in respect of whom a detention order has been made shall be liable—

Power to regulate place and conditions of detention.

(a) to be detained in such place and under such conditions including conditions as to maintenance, interviews or communication with others, discipline and punishment for breaches of discipline, as the appropriate Government may, by general or special order, specify; and

(b) to be removed from one place of detention to another place of detention, whether within the same State or in another State by order of the appropriate Government;

Provided that no order shall be made by a State Government under clause (b) for the removal of a person from one State to another State except with the consent of the Government of that other State.

6. Where a person has been detained in pursuance of an order of detention under sub-section (1) of section 3 which has been made on two or

Grounds of

detention
severable.

more grounds, such order of detention shall be deemed to have been made separately on each of such grounds and accordingly—

(a) such order shall not be deemed to be invalid, or inoperative merely because one or some of the grounds is or are—

(i) vague,

(ii) non-existent,

(iii) not relevant,

(iv) not connected or not proximately connected with such person, or

(v) invalid for any other reason whatsoever,

and it is not therefore possible to hold that the Government or officer making such order would have been satisfied as provided in sub-section (1) of section 3 with reference to the remaining ground or grounds and made the order of detention;

(b) the Government or officer making the order of detention shall be deemed to have made the order of detention under the said sub-section (1) after being satisfied as provided in that sub-section with reference to the remaining ground or grounds.

Detention
orders
not to
be in-
valid or
inopera-
tive on
certain
grounds.

7. No detention order shall be invalid or inoperative merely by reason—

(a) that the person to be detained thereunder is outside the limits of the territorial jurisdiction of the Government or the officer making the order of detention; or

(b) that the place of detention of such person is outside the said limits.

Powers in
relation
to abscond-
ing
persons.

8. (1) If the appropriate Government has reason to believe that a person in respect of whom a detention order has been made has absconded or is concealing himself so that the order cannot be executed, that Government may—

(a) make a report in writing of the fact to a Metropolitan Magistrate or a Magistrate of the first class having jurisdiction in the place where the said person ordinarily resides; and thereupon the provisions of sections 82, 83, 84 and 85 of the Code of Criminal Procedure, 1973 shall apply in respect of the said person and his property as if the order directing that he be detained were a warrant issued by the Magistrate;

(b) by order notified in the Official Gazette direct the said person to appear before such officer, at such place and within such period as may be specified in the order; and if the said person fails to comply with such direction, he shall, unless he proves that it was not possible for him to comply therewith and that he had, within the period specified in the order, informed the officer mentioned in the order of the reason which rendered compliance therewith impossible and of his whereabouts, be punishable with imprisonment for a term which may extend to one year, or with fine, or with both.

2 of 1974.

(2) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under clause (b) of sub-section (1) shall be cognizable.

9. For the purposes of sub-clause (a) of clause (4) and sub-clause (c) of clause (7) of article 22 of the Constitution,—

Advisory
Boards.

(a) the Central Government and each State Government shall, whenever necessary, constitute one or more Advisory Boards each of which shall consist of a Chairman and two other persons possessing the qualifications specified in sub-clause (a) of clause (4) of article 22 of the Constitution;

(b) save as otherwise provided in section 10, the appropriate Government shall, within five weeks from the date of detention of a person under a detention order, make a reference in respect thereof to the Advisory Board constituted under clause (a) to enable the Advisory Board to make the report under sub-clause (a) of clause (4) of article 22 of the Constitution;

(c) the Advisory Board to which a reference is made under clause (b) shall after considering the reference and the materials placed before it and after calling for such further information as it may deem necessary from the appropriate Government or from any person called for the purpose through the appropriate Government or from the person concerned, and if, in any particular case, it considers it essential so to do or if the person concerned desires to be heard in person, after hearing him in person, prepare its report specifying in a separate paragraph thereof its opinion as to whether or not there is sufficient cause for the detention of the person concerned and submit the same within eleven weeks from the date of detention of the person concerned;

(d) when there is a difference of opinion among the members forming the Advisory Board, the opinion of the majority of such members shall be deemed to be the opinion of the Board;

(e) a person against whom an order of detention has been made under this Act shall not be entitled to appear by any legal practitioner in any matter connected with the reference to the Advisory Board and the proceedings of the Advisory Board and its report, excepting that part of the report in which the opinion of the Advisory Board is specified, shall be confidential;

(f) in every case where the Advisory Board has reported that there is in its opinion sufficient cause for the detention of a person, the appropriate Government may confirm the detention order and continue the detention of the person concerned for such period as it thinks fit and in every case where the Advisory Board has reported that there is in its opinion no sufficient cause for the detention of the person concerned, the appropriate Government shall revoke the detention order and cause the person to be released forthwith.

Cases in which and circumstances under which persons may be detained for periods longer than three months without obtaining the opinion of Advisory Board.

10. (1) Notwithstanding anything contained in this Act, any person (including a foreigner) in respect of whom an order of detention is made under this Act at any time before the 31st day of July, 1990, may be detained without obtaining, in accordance with the provisions of sub-clause (a) of clause (4) of article 22 of the Constitution, the opinion of an Advisory Board for a period longer than three months but not exceeding six months from the date of his detention, where the order of detention has been made against such person with a view to preventing him from engaging in traffic in narcotic drugs and psychotropic substances, and the Central Government or any officer of the Central Government, not below the rank of an Additional Secretary to that Government, specially empowered for the purposes of this section by that Government, is satisfied that such person engages or is likely to engage in illicit traffic in narcotic drugs and psychotropic substances into, out of, through or within any area highly vulnerable to such illicit traffic and makes a declaration to that effect within five weeks of the detention of such person.

Explanation 1.—In this sub-section, "area highly vulnerable to such illicit traffic" means—

(i) the Indian customs waters;

(ii) the customs airports;

(iii) the metropolitan cities of Bombay, Calcutta, Delhi, Madras and the city of Varanasi;

(iv) the inland area one hundred kilometres in width from the coast of India falling within the territories of the States of Andhra Pradesh, Goa, Gujarat, Karnataka, Kerala, Maharashtra, Orissa, Tamil Nadu and West Bengal and the Union territories of Daman and Diu and Pondicherry;

(v) the inland area one hundred kilometres in width from—

(a) the India-Pakistan border in the States of Gujarat, Punjab and Rajasthan;

(b) the India-Nepal border in the States of Bihar, Sikkim, Uttar Pradesh and West Bengal;

(c) the India-Burma border in the States of Arunachal Pradesh, Manipur, Mizoram and Nagaland;

(d) the India-Bangladesh border in the States of Assam, Meghalaya, Tripura and West Bengal;

(e) the India-Bhutan border in the States of Arunachal Pradesh, Assam, Sikkim and West Bengal;

(vi) such other area or customs station, as the Central Government may, having regard to the vulnerability of such area or customs station, as the case may be, to illicit traffic, by notification in the Official Gazette, specify in this behalf.

Explanation 2.—For the purposes of Explanation 1, "customs station" has the same meaning as in clause (13) of section 2 of the Customs Act, 1962.

(2) In the case of any person detained under a detention order to which the provisions of sub-section (1) apply, section 9 shall have effect subject to the following modifications, namely:—

(i) in clause (b), for the words "shall, within five weeks", the words "shall, within four months and two weeks" shall be substituted;

(ii) in clause (c),—

(a) for the words "the detention of the person concerned", the words "the continued detention of the person concerned" shall be substituted;

(b) for the words "eleven weeks", the words "five months and three weeks" shall be substituted;

(iii) in clause (f), for the words "for the detention", at both the places where they occur, the words "for the continued detention" shall be substituted.

11. The maximum period for which any person may be detained in pursuance of any detention order to which the provisions of section 10 do not apply and which has been confirmed under clause (f) of section 9 shall be one year from the date of detention, and the maximum period for which any person may be detained in pursuance of any detention order to which the provisions of section 10 apply and which has been confirmed under clause (f) of section 9, read with sub-section (2) of section 10, shall be two years from the date of detention:

Maximum period of detention.

Provided that nothing contained in this section shall affect the power of appropriate Government in either case to revoke or modify the detention order at any earlier time.

10 of 1897. 12. (1) Without prejudice to the provisions of section 21 of the General Clauses Act, 1897, a detention order may, at any time, be revoked or modified—

Revocation of detention orders.

(a) notwithstanding that the order has been made by an officer of a State Government, by that State Government or by the Central Government;

(b) notwithstanding that the order has been made by an officer of the Central Government or by a State Government, by the Central Government.

(2) The revocation of a detention order shall not bar the making of another detention order under section 3 against the same person.

13. (1) The Central Government may, at any time, direct that any person detained in pursuance of a detention order made by that Government or by an officer subordinate to that Government or by a State Government or by an officer subordinate to a State Government, may be released for any specified period either without conditions or upon such conditions specified in the direction as that person accepts, and may, at any time, cancel his release.

Temporary release of persons detained.

(2) A State Government may, at any time, direct that any person detained in pursuance of a detention order made by that Government or by an officer subordinate to that Government may be released for any specified period either without conditions or upon such conditions

specified in the direction as the person accepts, and may, at any time, cancel his release.

(3) In directing the release of any person under sub-section (1) or sub-section (2), the Government directing the release may require him to enter into a bond with sureties for the due observance of the conditions specified in the direction.

(4) Any person released under sub-section (1) or sub-section (2) shall surrender himself at the time and place, and to the authority, specified in the order directing his release, or cancelling his release, as the case may be.

(5) If any person fails without sufficient cause to surrender himself in the manner specified in sub-section (4), he shall be punishable with imprisonment for a term which may extend to two years, or with fine, or with both.

(6) If any person released under sub-section (1) or sub-section (2) fails to fulfil any of the conditions imposed upon him under the said sub-section or in the bond entered into by him, the bond shall be declared to be forfeited and any person bound thereby shall be liable to pay the penalty thereof.

(7) Notwithstanding anything contained in any other law and save as otherwise provided in this section, no person against whom a detention order made under this Act is in force shall be released whether on bail or 'bail bond or otherwise.

14. No suit or other legal proceeding shall lie against the Central Government or a State Government and no suit, prosecution or other legal proceeding shall lie against any person for anything in good faith done or intended to be done in pursuance of this Act.

15. In section 3 of the Conservation of Foreign Exchange and Prevention of Smuggling Activities Act, 1974, to sub-section (1), the following proviso shall be added, namely:—

"Provided that no order of detention shall be made on any of the grounds specified in this sub-section on which an order of detention may be made under section 3 of the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988 or, under section 3 of the Jammu and Kashmir Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Ordinance, 1988."

16. (1) The Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Ordinance, 1988, is hereby repealed.

(2) Notwithstanding such repeal, anything done or any action taken under the said Ordinance shall be deemed to have been done or taken under the corresponding provisions of this Act.

S. RAMAIAH,
Secy. to the Govt. of India.

Protec-
tion of
action
taken in
good
faith,

Amend-
ment of
Act 52
of 1974.

Repeal
and
saving.

J. & K.
Ordi-
nance
1 of 1988.
Ord. 7 of
1988.

रजिस्ट्रार सं. डी-डी-72

REGISTERED No. D-(D)-72



भारत का राजपत्र

The Gazette of India

EXTRAORDINARY

भाग II—खण्ड 1

PART II—Section 1

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 75] नई दिल्ली, सोमवार, सितम्बर 16, 1985/भाद्र 25, 1907
 No. 75] NEW DELHI, MONDAY, SEPTEMBER 16, 1985/BHADRA 25, 1907

इस भाग में मिल चुक संख्या दो वाली है जिसमें कि यह समय संकलन
 के रूप में रखा जा सके।

Separate paging is given to this Part in order that it may be filed
 as a separate compilation

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the 16th September, 1985/Bhadra 25, 1907 (Saka)

The following Act of Parliament received the assent of the President on the 16th September, 1985, and is hereby published for general information:—

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, 1985

No. 61 of 1985

[16th September, 1985.]

An Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances and for matters connected therewith.

Be it enacted by Parliament in the Thirty-sixth Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

1. (1) This Act may be called the Narcotic Drugs and Psychotropic Substances Act, 1985.

(2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint, and different dates

Short
title,
extent
and
com-
mence-
ment

(2) The Narcotics Commissioner shall, either by himself or through officers subordinate to him, exercise all powers and perform all functions relating to the superintendence of the cultivation of the opium poppy and production of opium and shall also exercise and perform such other powers and functions as may be entrusted to him by the Central Government.

(3) The officers appointed under sub-section (1) shall be subject to the general control and direction of the Central Government, or, if so directed by that Government, also of the Board or any other authority or officer.

6. (1) The Central Government may constitute, by notification in the Official Gazette, an advisory committee to be called "The Narcotic Drugs and Psychotropic Substances Consultative Committee" (hereafter in this section referred to as the Committee) to advise the Central Government on such matters relating to the administration of this Act as are referred to it by that Government from time to time.

The Narcotic Drugs and Psychotropic Substances Consultative Committee.

(2) The Committee shall consist of a Chairman and such other members, not exceeding twenty, as may be appointed by the Central Government.

(3) The Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

(4) The Committee may, if it deems it necessary so to do for the efficient discharge of any of its functions, constitute one or more sub-committees and may appoint to any such sub-committee, whether generally or for the consideration of any particular matter, any person (including a non-official) who is not a member of the Committee.

(5) The term of office of, the manner of filling casual vacancies in the offices of and the allowances, if any, payable to, the Chairman and other members of the Committee, and the conditions and restrictions subject to which the Committee may appoint a person who is not a member of the Committee as a member of any of its sub-committees, shall be such as may be prescribed by rules made by the Central Government.

7. (1) The State Government may appoint such officers with such designations as it thinks fit for the purposes of this Act.

Officers of State Government.

(2) The officers appointed under sub-section (1) shall be subject to the general control and direction of the State Government, or, if so directed by that Government, also of any other authority or officer.

CHAPTER III

PROHIBITION, CONTROL AND REGULATION

8. No. person shall—

(a) cultivate any coca plant or gather any portion of coca plant; or

(b) cultivate the opium poppy or any cannabis plant; or

(c) produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-State, export inter-State, import

Prohibition of certain operations.

into India, export from India or tranship any narcotic drug or psychotropic substance,

except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the rules or orders made thereunder and in a case where any such provision, imposes any requirement by way of licence, permit or authorisation also in accordance with the terms and conditions of such licence, permit or authorisation:

Provided that, and subject to the other provisions of this Act and the rules made thereunder, the prohibition against the cultivation of the cannabis plant for the production of ganja or the production, possession, use, consumption, purchase, sale, transport, warehousing, import inter-State and export inter-State of ganja for any purpose other than medical and scientific purpose shall take effect only from the date which the Central Government may, by notification in the Official Gazette, specify in this behalf.

Power of
Central
Govern-
ment to
permit,
control
and re-
gulate.

9. (1) Subject to the provisions of section 8, the Central Government may, by rules—

(a) permit and regulate—

(i) the cultivation, or gathering of any portion (such cultivation or gathering being only on account of the Central Government) of coca plant, or the production, possession, sale, purchase, transport, import inter-State, export inter-State, use or consumption of coca leaves;

(ii) the cultivation (such cultivation being only on account of Central Government) of the opium poppy;

(iii) the production and manufacture of opium and production of poppy straw;

(iv) the sale of opium and opium derivatives from the Central Government factories for export from India or sale to State Government or to manufacturing chemists;

(v) the manufacture of manufactured drugs (other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess;

(vi) the manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption or use of psychotropic substances;

(vii) the import into India and export from India and transhipment of narcotic drugs and psychotropic substances;

(b) prescribe any other matter requisite to render effective the control of the Central Government over any of the matters specified in clause (a).

(2) In particular and without prejudice to the generality of the foregoing power, such rules may—

(a) empower the Central Government to fix from time to time the limits within which licences may be given for the cultivation of the opium poppy;

(b) require that all opium, the produce of land cultivated with the opium poppy, shall be delivered by the cultivators to the officers authorised in this behalf by the Central Government;

(c) prescribe the forms and conditions of licences for cultivation of the opium poppy and for production and manufacture of opium; the fees that may be charged therefor; the authorities by which such licences may be granted, withheld, refused or cancelled and the authorities before which appeals against the orders of withholding, refusal or cancellation of licences shall lie;

(d) prescribe that opium shall be weighed, examined and classified according to its quality and consistence by the officers authorised in this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator;

(e) empower the Central Government to fix from time to time the price to be paid to the cultivators for the opium delivered;

(f) provide for the weighing, examination and classification, according to the quality and consistence, of the opium received at the factory and the deductions from or additions (if any) to the standard price to be made in accordance with the result of such examination; and the authorities by which the decisions with regard to the weighing, examination, classification, deductions or additions shall be made and the authorities before which appeals against such decisions shall lie;

(g) require that opium delivered by a cultivator, if found as a result of examination in the Central Government factory to be adulterated, may be confiscated by the officers authorised in this behalf;

(h) prescribe the forms and conditions of licences for the manufacture of manufactured drugs, the authorities by which such licences may be granted and the fees that may be charged therefor;

(i) prescribe the forms and conditions of licences or permits for the manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption or use of psychotropic substances, the authorities by which such licences or permits may be granted and the fees that may be charged therefor;

(j) prescribe the ports and other places at which any kind of narcotic drugs or psychotropic substances may be imported into India or exported from India or transhipped; the forms and conditions of certificates, authorisations or permits, as the case may be, for such import, export or transhipment; the authorities by which such certificates, authorisations or permits may be granted and the fees that may be charged therefor.

10. (1) Subject to the provisions of section 8, the State Government may, by rules—

(a) permit and regulate—

(i) the possession, transport, import inter-State, export inter-State warehousing, sale, purchase, consumption and use of poppy straw,

Power of
State
Govern-
ment to
permit,
control
and regu-
late.

(ii) the possession, transport, import inter-State, export inter-State, sale, purchase, consumption and use of opium;

(iii) the cultivation of any cannabis plant, production, manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption or use of cannabis (excluding *charras*);

(iv) the manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess;

(v) the possession, transport, purchase, sale, import inter-State, export inter-State, use or consumption of manufactured drugs other than prepared opium and of coca leaf and any preparation containing any manufactured drug;

(vi) the manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption;

Provided that save in so far as may be expressly provided in the rules made under sub-clauses (iv) and (v), nothing in section 8 shall apply to the import inter-State, export inter-State, transport, possession, purchase, sale, use or consumption of manufactured drugs which are the property and in the possession of the Government:

Provided further that such drugs as are referred to in the preceding proviso shall not be sold or otherwise delivered to any person who, under the rules made by the State Government under the aforesaid sub-clauses, is not entitled to their possession;

(b) prescribe any other matter requisite to render effective the control of the State Government over any of the matters specified in clause (a).

(2) In particular and without prejudice to the generality of the foregoing power, such rules may—

(a) empower the State Government to declare any place to be a warehouse wherein it shall be the duty of the owners to deposit all such poppy straw as is legally imported inter-State and is intended for export inter-State or export from India; to regulate the safe custody of such poppy straw warehoused and the removal of such poppy straw for sale or export inter-State or export from India; to levy fees for such warehousing and to prescribe the manner in which and the period after which the poppy straw warehoused shall be disposed of in default of payment of fees;

(b) provide that the limits within which licences may be given for the cultivation of any cannabis plant shall be fixed from time to time by or under the orders of the State Government;

(c) provide that only the cultivators licenced by the prescribed authority of the State Government shall be authorised to engage in cultivation of any cannabis plant;

(d) require that all cannabis, the produce of land cultivated with cannabis plant, shall be delivered by the cultivators to the officers of the State Government authorised in this behalf;

(e) empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered;

(f) prescribe the forms and conditions of licences or permits for the purposes specified in sub-clauses (i) to (vi) of clause (c) of subsection (1) and the authorities by which such licences or permits may be granted and the fees that may be charged therefor.

11. Notwithstanding anything to the contrary contained in any law or contract, no narcotic drug, psychotropic substance, coca plant, the opium poppy or cannabis plant shall be liable to be distrained or attached by any person for the recovery of any money under any order or decree of any court or authority or otherwise.

Narcotic drugs and psychotropic substances, etc., not liable to distress or attachment.

12. No person shall engage in or control any trade whereby a narcotic drug or psychotropic substance is obtained outside India and supplied to any person outside India save with the previous authorisation of the Central Government and subject to such conditions as may be imposed by that Government in this behalf.

Restrictions over external dealings in narcotic drugs and psychotropic substances.

13. Notwithstanding anything contained in section 8, the Central Government may permit, with or without conditions, and on behalf of Government, the cultivation of any coca plant or gathering of any portion thereof or the production, possession, sale, purchase, transport, import inter-State, export inter-State or import into India of coca leaves for use in the preparation of any flavouring agent which shall not contain any alkaloid and to the extent necessary for such use.

Special provisions relating to coca plant and coca leaves for use in the preparation of flavouring agent.

14. Notwithstanding anything contained in section 8, Government may, by general or special order and subject to such conditions as may be specified in such order, allow cultivation of any cannabis plant for industrial purposes only of obtaining fibre or seed or for horticultural purposes.

Special provision relating to cannabis.

CHAPTER IV

OFFENCES AND PENALTIES

Punish-
ment for
contra-
vention
in rela-
tion to
poppy
straw.

15. Whoever, in contravention of any provision of this Act or any rule or order made or condition of a licence granted thereunder, produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw or removes or does any act in respect of warehoused poppy straw, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

Punish-
ment for
contra-
vention
in rela-
tion to
coca
plant and
coca
leaves.

16. Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder, cultivates any coca plant or gathers any portion of a coca plant or produces, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses coca leaves, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

Punish-
ment for
contra-
vention
in rela-
tion to
pre-
pared
opium.

17. Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses prepared opium shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

Punish-
ment for
contra-
vention
in rela-
tion to
opium
poppy
and
opium.

18. Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder cultivates the opium poppy or produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses opium shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

19. Any cultivator licensed to cultivate the opium poppy on account of the Central Government who embezzles or otherwise illegally disposes of the opium produced or any part thereof, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees;

Punishment for embezzlement of opium by cultivator.

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

20. Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder,—

Punishment for contravention in relation to cannabis plant and cannabis.

(a) cultivates any cannabis plant; or

(b) produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses cannabis,

shall be punishable,—

(i) where such contravention relates to *ganja* or the cultivation of cannabis plant, with rigorous imprisonment for a term which may extend to five years and shall also be liable to fine which may extend to fifty thousand rupees;

(ii) where such contravention relates to cannabis other than *ganja*, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees and which may extend to two lakh rupees;

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

21. Whoever, in contravention of any provision of this Act, or any rule or order made or condition of licence granted thereunder manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any manufactured drug or any preparation containing any manufactured drug shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Punishment for contravention in relation to manufactured drugs and preparations.

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

22. Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State, or uses any psychotropic substance shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Punishment for contravention in relation to psychotropic substances.

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

RETTYPED FROM ORIGINAL FOR CLARITY

JOINT MEDIA
STATEMENT

(Joint Statement by the Minister for Industry, Technology and Commerce, Senator John Button, and the Minister for Community Services and Health, Dr. Neal Blevett, MP)

IMMEDIATE RELEASE

25 MAY 1988

79/88

PHARMACEUTICAL PRODUCTS INDUSTRY: PRICING GUIDELINES

The Minister for Industry, Technology and Commerce, Senator John Button, and the Minister for Community Services and Health, Dr. Neal Blevett, jointly announced today that they had accepted the recommendations of the Pharmaceutical Benefits Pricing Authority on how best to give effect to the revised pricing guidelines for pharmaceutical products aimed at further developing the pharmaceuticals industry in Australia.

"A fundamental feature of the guidelines is that they will encourage local product development and enhancement on an internationally competitive basis - an essential ingredient to the long term viability of this industry," they said.

The broad principles behind the guidelines were that companies prepared to meet, or commit themselves to meet, industry development criteria, relating particularly to exports and product development, would become eligible for improved prices. These prices, however, would be limited to ensure that they did not exceed world prices and were reasonable, having regard to new activities proposed by the companies. The price increments would be paid directly to manufacturers on a quarterly basis.

The Ministers commented that price increases would be influenced by a number of factors, including growth in export and research and development activity. While the Authority had proposed closely defined links between price increases and industry activity, especially exports and research and development, it has recognized that there will be circumstances where judgment rather than quantitative rules will be more appropriate.

The Ministers expected that progressive firms in the industry would gain considerable benefit from the pricing package. However, they recognized that further refinement to the guidelines may be necessary. This would be done in consultation with the industry and in the light of the experience of companies in developing their proposals.

- 2 -

The Pricing Authority had also made recommendations on the implementation of pricing arrangements for out-of-patent products where there were lower priced brands available. Senator Button and Dr. Blevett said the Government had accepted these, but in the light of the time it had taken to develop the industry development guidelines, the implementation of these would be postponed to 1 December 1988.

The Ministers said they would encourage firms which were thinking of taking advantage of the improved pricing arrangements to contact the Authority at an early stage to discuss their proposals. The Authority would be happy to provide guidance and clarification as required.

The chairman of the Authority, Mr. Colin Conron, indicated to the Ministers that discussions would be held with the industry in Sydney and Melbourne in the near future to explain the pricing guidelines. Further details would be available shortly from Mr. Alan Stevens, Acting Secretary to the Authority (Tel 062-898583).

Detail of the revised pricing arrangements are attached.

CANBERRA**Contacts:**

Department of Industry
Technology & Commerce

Jack McGuire
(062) 761640 (W)
(062) 476838 (H)

Senator Button's Office
Laurie Viggins
(062) 733489 (W)
(062) 883352 (H)

Department of Community
Services & Health
Mark Johnson
(062) 897085 (W)
(062) 303537 (H)

ATTACHMENT

PHARMACEUTICAL BENEFITS PRICING AUTHORITYGuidelines on Pharmaceuticals Pricing ArrangementsHigher Prices For Australian Activity

Under the new pricing arrangements, the Pharmaceutical Benefits Pricing Authority will be able to recommend higher prices for those companies which are prepared to make a significant commitment to Australian manufacturing, product development and exports.

In order to qualify for higher prices, companies will be required to pass a number of performance hurdles in respect of exports and research and development. However, there will be scope for the Authority to make qualitative based assessments.

Principles

The Australian activity guidelines, under which the higher prices will be paid, and based on a number of fundamental principles, these being, that:

- . prices for drugs listed on the Pharmaceutical Benefits Scheme (PBS) should not be an impediment to the significant development of the industry;
- . higher prices should only be recommended if they are likely to contribute to the development of significant internationally competitive activity in Australia;
- . PBS prices should not exceed the prices which could be expected in a normal competitive market; and
- . a net benefit to the economy should result from any price increases granted on the basis of Australian activity.

Definitions

In those guidelines, the following definitions apply:

- . 'pharmaceuticals' refers to human-use pharmaceuticals (including biologically active products or systems) of the type currently available under the Pharmaceutical Benefits Scheme;
- . 'exports' includes exports of Australian made active ingredients and raw materials for use in pharmaceutical products. Case-by-case consideration will be given where pharmaceutical related services are being exported; and
- . 'value added' refers to the difference between the ex-factory selling price and the landed cost of imported ingredients and materials (including royalties and other similar payments).

Performance Requirements1. Quantitative

In order to qualify for higher prices under these arrangements, companies would need to satisfy all of the following performance requirements:

a) in respect of exports

- it would be necessary to have a minimum export/import ratio of 0.5 in relation to the output of pharmaceuticals, or demonstrate that it intends achieving this within three years
- exports would be required to grow, in real terms, by a minimum of 33 percent over the three year period following approval of any price increase granted under the Australian activity guideline
- only exports of pharmaceuticals manufactured locally (using either imported or locally sourced active ingredients) will qualify for consideration.

b) with respect to research and development

- the company would need to demonstrate a commitment to significant product innovation and development. It would be required to be spending in Australia, or show that it intends spending, a minimum of 3 percent of pharmaceutical turnover on research and development.
- spending on research and development would be expected to increase by at least 33 percent in real terms over the following three years.
- these research and development requirements can be waived where a firm establishes a major internationally competitive Australian plant for manufacture and export of active ingredients.
- in defining research and development the Authority will follow the definition adopted by the Industrial Research and Development Board for the purpose of applying the 150 percent tax concession; the above three percent requirement may need to be varied when the Board clarifies its definition.

If a company meets these quantitative performance requirements, it will automatically qualify for higher prices under the guidelines on Australian activity.

2. Qualitative

The Authority recognizes that there may be circumstances in which a company, while making a significant contribution to internationally competitive production in Australia, does not meet the quantitative measures outlined above. In such circumstances, the Authority may recommend higher prices if it is satisfied that the company concerned is substantially increasing its activity in this country and the activity is internationally competitive.

The purpose of this provision is not to by-pass the stringency or intent of the quantitative requirements, but rather to provide some flexibility in those cases where a company's development strategy is no less ambitious.

Pricing Arrangements

The maximum price payable for a PBS drug will be the world average price, and prices can range up to this level.

Actual price levels will be determined by the Authority having regard to the ex-manufacturer prices in other countries and the likely net benefits to the Australian economy of the increased activity. The dollar value of the higher prices paid to a company under the activity guideline will generally not exceed 25 percent of the dollar value associated with the increased Australian activity.

- for this purpose, increased Australian activity will be:
 - a) the increase in value added for domestic sales of pharmaceuticals (excluding the impact of changes in volume or price);
 - b) the increase in value added and/or volume for export sales of pharmaceuticals (excluding the impact of price changes); and
 - c) the increase in expenditure on pharmaceutical research and development
- the Authority has the discretion to vary the 25 percent ratio if a company is able to demonstrate that a particular project involves larger net benefits than implied by this figure
- in those cases where a company's research and development expenditure is attracting the concessional tax deduction, the cost of price increases granted under the Australian activity guideline will not exceed 50 percent of the increases in post-tax expenditure on R & D (ie after allowing for the 150 percent tax deduction)

- 6 -

- the Authority may recommend higher prices on the basis of either current or planned increases in value added, but any future increases will be discounted to present value using, at least, the long-term rate
- the base year will be 1987.

The above provisions will apply to both new and existing drugs. While firms will have considerable discretion as to the products which attract higher prices, the Authority will normally expect Australian activity related price increases to apply to products with a substantial local value added.

Where products are subject to competition from out of patent products, price increases will be limited by the Government's pricing policy for such products, which provides for a maximum price differential of 20 cents between brands.

Transitional Pricing Arrangements

Price increases granted under the Australian activity guideline will not increase a company's average PBS prices by more than 10 percent from one year to the next.

Performance Monitoring and Price Review

Where a company has benefited from local activity related price increases, its performance, in respect of value added, exports and R & D activity, will be monitored annually to ensure that the relationship between the price increases and the likely benefits is being maintained.

The Authority will also monitor the firm's profitability with respect to pharmaceuticals to ensure that it does not become excessive by comparison with similar industries.

Except where adjustments are required under the above monitoring provisions, it is envisaged that incremental price increases will continue until at least the foreshadowed review, in five years, of the pricing guidelines.

Pricing Differential for Out of Patent Products

The Government's pricing policy for out of patent products provides for a 20 cent maximum price differential between alternate brands of the same drug. This rule will be applied to those drugs where a cheaper alternative brand is reasonably available in the market place.

Within this guideline a brand will be considered to be reasonably available if:

- it is marketed in all States; and
- the supplier has the capacity to meet, if necessary, the full PBS demand for it within four months of being notified that other manufacturers are withdrawing their brands.

- 7 -

In those cases where at least 10 percent of the prescriptions for a drug are written for the lowest priced brand, the market test will generally be satisfied. Where at least 10 percent of prescriptions are written in generic terms (ie. no brand specified), the lowest priced brand will normally be accepted as meeting the availability criterion, unless evidence is available to suggest the supplier of that brand is unable to meet full demand if necessary.

In determining reasonable market availability, the Authority will seek information as required from suppliers.

Where two or more brands have the same lowest price, the market test will be applied as if the brands were one.

ATTACHMENT IX

SPRENGER & LANG

ATTORNEYS AT LAW

I.S. WEISSBRODT* OF COUNSEL
 PAUL C. SPRENGER**
 JANE LANG**
 NITRA H. BARROW**
 REBECCA S. TROTIN*
 JEAN H. SOLER*

*ADMITTED IN THE DISTRICT OF COLUMBIA
 **ADMITTED IN MINNESOTA
 *ADMITTED IN NEW YORK AND VIRGINIA

1814 TWENTIETH STREET, N.W.
 WASHINGTON, D.C. 20008
 (202) 285-6010
 FAX (202) 232-4852

225 WIDGEWOOD AVENUE
 MINNEAPOLIS, MINNESOTA 55403
 (612) 871-6810
 FAX (612) 871-6270

REPLY TO

UNITED STATES NARCOTIC RAW MATERIALS IMPORT POLICY:AN HISTORICAL ANALYSIS OF THE "80-20" RULE

A Memorandum Prepared for Mallinckrodt, Inc.

by Jane Lang, Esq.
 Washington, D.C.

August 1989

I. INTRODUCTION

Essential pharmaceuticals, including codeine, morphine and thebaine derivatives, are produced from the opium poppy, known as *Papaver somniferum*, for therapeutic purposes. However, in the illicit trade, the morphine derived from opium is converted into heroin, a highly addictive and widely-abused drug. There is, accordingly, a long history of national and international efforts to control the worldwide production, distribution and use of the opium poppy, and its narcotic derivatives. The objective of international regulation has always been to assure sufficient licit production of the opium poppy to meet legitimate medical and scientific needs for opium derivatives, but to avoid over-production which could feed the illicit traffic.

There are two methods of extracting morphine, codeine and thebaine from the opium poppy. One method utilizes opium gum¹ as the raw material. Opium gum is obtained from the opium poppy by lancing the capsule of the plant and collecting the exuded gum. The other extraction method utilizes the dry capsules or "poppy straw" and produces a liquid concentrate of the contained

¹ The terms "gum opium," "opium gum" and "opium" are used interchangeably in this memorandum.

Memorandum, "80-20" Rule
 Page 2
 August 1989

alkaloids, or concentrate of poppy straw (CPS).^{*} CPS is stored and sold as a dry powder. Most of the thebaine is lost during the natural maturation of the opium "poppy straw" and also in the CPS manufacturing process.

Until the 1970's, opium was the sole narcotic raw material lawfully imported into the United States, and Turkey and India were the sole suppliers. However, a worldwide shortage of licit opium developed in the early 1970's as a result of poor crops in India and the abandonment of opium production by Turkey. Consequently, in 1975, the Drug Enforcement Administration (DEA) authorized the importation of CPS on an emergency basis to meet medical needs. Since that time, both CPS and gum opium have been utilized for the production of licit narcotic drugs in the United States. India remains the sole supplier of opium. France and Yugoslavia, joined in 1980 by Turkey, which converted to the CPS process, and Australia, export CPS to this country.

II. INTERNATIONAL EFFORTS TO CONTROL NARCOTIC DRUG PRODUCTION

A. Single Convention on Narcotic Drugs

The United Nations sponsored a conference seeking the adoption of a single convention on narcotic drugs. The parties recognized that narcotic drugs remained indispensable for medical purposes. They recognized as well that the illicit traffic in narcotic drugs constitutes a serious threat to the health and welfare of the individual and society. They sought an agreement to replace existing treaties on narcotic drugs, and to provide for on-going international cooperation and control.

The Single Convention on Narcotic Drugs was signed in 1961. The signatories agreed, among other measures, to control and limit the production of opium poppies. A system of estimates was established to determine the amount of opium required to meet the medical needs of each country. These estimates of needs, and reports on actual utilization and consumption of licit narcotics, were to be supplied annually to the International Narcotics Control Board (INCB).

^{*} A newer potential source of codeine is another type of poppy known as Papaver bracteatum. Unlike the opium poppy, this type of poppy produces only one alkaloid in measurable quantities, thebaine. Thebaine can be converted to codeine but is not readily convertible to morphine and heroin.

Memorandum, "80-20" Rule
 Page 3
 August 1989

Each opium producing country also agreed to establish and maintain a government agency to regulate the land cultivated for such purposes. Only farmers licensed by the agency could grow the opium poppy. The entire crop had to be sold to the government agency which was vested with the exclusive right to import and export gum opium.

Article 24, paragraph 3 of the Single Convention allows those countries which exported opium during the ten years immediately prior to January 1, 1961,³ to continue to do so without further approval by the INCB, as long as they regulate production in accordance with the Single Convention and assure that the opium they produce is not diverted into the illicit traffic. However, countries that propose to export opium for the first time after January 1, 1961, must first notify the Economic and Social Council of the U.N. (the "ECOSOC") to obtain approval. The objective of this procedure is to prevent over-production and diversion into the illicit traffic.

B. United Nations Resolutions 471 and 497

Following the opium shortage of the early and mid-1970's, a number of countries entered the CPS export business. As a result, the United Nations Commission on Narcotic Drugs (CND) became concerned about substantial over-production, and the correlative threat to international regulation of the licit narcotics market. The expansion of this market led the CND and ECOSOC to adopt two resolutions in 1979 and 1980.⁴ These resolutions, which were intended to promote the policies originally enunciated in the Single Convention, were supported by India and Turkey. India at that time was the only viable licit opium gum producer and exporter to the U.S. Turkey was to become the major producer and exporter of CPS. Both of these countries were signatories to the Single Convention and were defined there as "traditional" producers.

³ The ten countries covered by this definition were India, Turkey, Yugoslavia, Afghanistan, Burma, Bulgaria, Iran, Pakistan, Viet Nam, and the U.S.S.R.

⁴ It was considered easier to do this through the United Nations resolutions, than by amendment of the Single Convention. See State Dept. statement publ. 45 Fed. Reg. 9291-9293.

Memorandum, "80-20" Rule
 Page 4
 August 1989

Resolution 471 urged countries to adopt policies whereby importing countries would support "the traditional supply countries" to avoid the proliferation of producing and manufacturing sources for export. It also urged producing countries which "set up additional capacities in recent years," to restrict production programs. Resolution 497 is similar. However, it focuses on major producing and manufacturing countries that have set up additional capacity in recent years "for export" and urges them to restrict "substantially" their production level.

Australia, a CPS producer which did not export before 1961, argued for a broader construction of the Resolutions. It contended that they should extend to all producing countries that had invested heavily in production in recent years, including the traditional suppliers. The United States has never accepted that interpretation. It has consistently construed the Resolutions to encourage reliance on traditional suppliers engaged in the export business before 1961, and to discourage the proliferation of new suppliers.

III. U.S. NARCOTIC RAW MATERIALS IMPORT POLICIES

A. Existing Statutes and Regulations

The United States, in light of the United Nations Resolutions, reviewed its policies on importing narcotic raw materials. The United States policy had been to rely on imports of opium gum rather than to become self-sufficient, intending to "set an example to the world community to refrain from overproduction and to limit the number of opium-producing nations to a minimum." The Controlled Substances Act, part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, incorporates this policy. Moreover, it permits gum opium imports only in such amounts as the Attorney General finds necessary for medical, scientific or other legitimate purposes.

Under the original Act, the domestic manufacturers could import other narcotic raw materials, such as poppy straw and CPS, only during an emergency if domestic supplies were inadequate, or if competition among domestic manufacturers were inadequate. In 1975, a supply emergency was found to exist, and the importation of CPS and poppy straw was authorized. France, Yugoslavia, and

* 44 Fed. Reg. 33696 (June 12, 1979)

Memorandum, "80-20" Rule
 Page 5
 August 1989

Hungary for the first time became suppliers of these raw materials to the United States.*

Four years later, the supply situation had changed, as reflected in the CND resolutions. It was predicted that the narcotics manufacturing capacity would be 50% in excess of licit narcotics demand by 1982 when the new Turkish CPS processing plant would be fully operational. The United States, too, became concerned about overproduction, but it also recognized that it was no longer feasible to rely solely on opium gum, the sole supplier of which was India. Thus faced with competing international and domestic interests, in 1979, the DEA, in coordination with the State Department, proposed a new policy to implement the 1979 CND resolution. There followed a two-year rulemaking, discussed in greater detail below.

B. Adoption of a New Policy

At the end of the rulemaking procedure, the DEA revised its import regulations to permit the importation of poppy straw and CPS as well as opium gum in the absence of an emergency. It also established a quota system, known as the "80-20 rule," which enabled the United States to continue its long-standing reliance on imports from the traditional nations. At the same time, it provided flexibility to meet the realities of a growing market in CPS from other sources.

The 80-20 rule became effective in September 1981. 21 C.F.R. Section 1312.13(d). It prescribes that 80 percent of U.S. imports of narcotic raw materials must come from India and Turkey in the form of opium gum and CPS. The remaining 20 percent, in the form of poppy straw and CPS, may be obtained from five other countries: Yugoslavia, Australia, Hungary, France, and Poland.

IV. ANTI-DRUG ABUSE ACT OF 1988

United States narcotics raw material import policy is again under review as a result of the enactment of the Anti-Drug Abuse Act of 1988. P.L. 100-690. Pursuant to Section 4307, the

* Australia became a CPS supplier to the U.S. only after the 80-20 rule was adopted.

' As a practical matter, the United States does not import poppy straw.

Memorandum, "80-20" Rule
 Page 6
 August 1989

President must report to Congress the results of a study of its narcotics raw material policy to determine:

- (1) the international needs for opium-derived products, and the ability to meet those needs from opium gum and CPS;
- (2) whether the United States should continue to rely solely on India for opium gum;
- (3) whether the United States should encourage all producers of licit opium to use CPS; and
- (4) what options the United States has to reduce its reliance on licit opium gum from India.

In the course of this study, the 80-20 rule, as well as the continued importation of opium from India, are being re-examined. This Memorandum examines the background of the 80-20 rule to provide an understanding of its history and intent.

V. SUMMARY OF THE 80-20 RULEMAKING

A. Advanced Notice of Proposed Rulemaking (ANPR)

DEA first published an Advanced Notice of Proposed Rulemaking (ANPR) on June 12, 1979. 44 Fed. Reg. 33695. It proposed that United States importers of opium, poppy straw and poppy straw concentrate be restricted to purchases from the "traditional" countries, i.e. India and Turkey, with certain limited exceptions. The proposal consisted of four points:

1. Authorization of imports of gum opium from a country that during ten years immediately before 1961 exported opium it produced, and that has adequate controls;
2. Authorization of imports of poppy straw from a country which qualified under number 1 above;
3. Authorization of CPS imports from a country which (a) qualified under number 1 above, or (b) produces CPS from poppy straw from such a country and itself has adequate controls over narcotic raw materials;
4. Exceptions for imports from other countries to honor contracts of U.S. companies signed prior to January 1, 1979, or to ensure sufficient supplies at reasonable prices.

Memorandum, "80-20" Rule
Page 7
August 1989

B. State Department Support for the Proposed Rule

The State Department, in a letter to the DEA, supported the rule contemplated in the ANPR.^{*} Unlike the U.S. Trade Representative (USTR) who urged adoption of a quota, the State Department advocated the DEA approach which placed primary reliance on traditional suppliers for U.S. imports of narcotic raw materials. Reliance on imports from the traditional suppliers would achieve the U.S. objective of balancing supply and demand, thereby lessening the danger that excess supplies would be diverted to the illicit market. The State Department attributed overproduction, and the corresponding increase in illicit traffic, to entry of more producing countries into the market, rather than to overproduction by the traditional producing nations. It saw the problem created by rapid increase in morphine production and export by nontraditional suppliers, such as Australia and France. This resulted in large stocks of unsold opium and CPS in producing countries, enhancing the risk of diversion for illicit purposes.

In its response to the ANPR, the State Department analyzed the effects of the proposed policy on other nations, and concluded it would not have adverse consequences, based on the following:

- a. Of the ten countries defined as traditional suppliers under the Single Convention, India was the only country exporting gum opium to the U.S. It would retain that opportunity under the proposed rule.
- b. Under the proposed rule, the U.S. could import CPS only if it was produced from poppies grown by traditional suppliers. Among the traditional suppliers, only Yugoslavia exported significant quantities of CPS into the U.S., beginning in the late 1970's. Turkey, which would begin processing CPS later in 1980, would be an eligible exporter since it was a traditional supplier. Hungarian imports would also be permitted if they used Turkish-grown poppy straw.
- c. France, which then accounted for 28% of U.S. imports, grows its own poppy straw, but the U.S. could continue to import from France under existing contracts until

^{*} The letter was set forth in its entirety in the DEA notice of February 12, 1980, 45 Fed. Reg. 9291-9293.

Memorandum, "80-20" Rule
Page 8
August 1989

mid-1982. The Netherlands and Australia would be excluded from the U.S. market because they manufacture CPS from their own poppy straw. However, this would not adversely impact those countries because at that time they did not export to the U.S.

The State Department emphasized most heavily its concern for maintaining controls against diversion from the licit market. India and Turkey maintained effective control systems, purchasing narcotics materials from their licensed growers, and ordering substantial reductions in licensed opium poppy acreage. It would be difficult for these countries to continue these measures, if nontraditional producers, such as Australia, came into the market. It would be hard to predict the impact on traditional producers if they lost their legal outlet. In short, the State Department was concerned that a change away from the traditional suppliers would encourage illicit heroin traffic from the Mideast into the U.S.

From the State Department's perspective, it was unlikely that continued reliance on imports from India, Turkey and Yugoslavia would lead to increased production by the other traditional nations. Bulgaria, Turkey, the U.S.S.R. and Yugoslavia could conceivably go back to opium, but labor costs and large investments in poppy straw and CPS made that unlikely. Gum opium was still produced, either licitly or illicitly, in Afghanistan, Burma, Iran, Pakistan, and Viet Nam. However, since they do not have effective control systems, they would not qualify as licit suppliers under the Single Convention.

C. Notice of Proposed Rulemaking

Following receipt of comments on the ANPR, DEA published a Notice of Proposed Rulemaking on February 12, 1980 with a more detailed version of the proposed rule. 45 Fed. Reg. 9289. The rule clarified that CPS could be imported from one of the traditional suppliers, or from a country utilizing poppy straw produced in one of those countries. It also specified and limited the exception provisions to contracts with four countries: Australia, Hungary, France and Poland.

In its preamble to the proposed rule, DEA addressed comments it had received on the 1979 ANPR. Opponents of the rulemaking argued that the proposed policy was inconsistent with international trade agreements and treaties, as well as U.S. statutes. The authority for the DEA to promulgate such a regulation was questioned. However, the DEA concluded it was

Memorandum, "80-20" Rule
Page 9
August 1989

neither contrary to the Single Convention, nor beyond the authority of the DEA to limit imports in order to avoid proliferation of narcotic producers, which was the very purpose of this regulation.

Australia, Hungary, France and Poland all objected to the proposed rule. France and Australia, neither of which was a traditional supplier, argued it was discriminatory because it excluded so many nations from the U.S. market. The DEA disagreed. Although the U.S. had been importing from Francopia, a French domestic manufacturer of CPS, it never gave any assurances of continuing future demand. Moreover, the United States was not discriminating against other countries. Rather, it was treating them exactly as it treated itself, having agreed to rely on the traditional suppliers rather than to develop a capacity for domestic production of raw materials.*

Hungary and Poland claimed they qualified as "traditional" suppliers, in that they had a long history of manufacturing CPS, and therefore should not be excluded from the U.S. market. However, DEA noted that they had only recently been allowed to export to the U.S. on an emergency basis.

Commentators also challenged the assumption that the proliferation of supplier nations, rather than increased production from traditional nations, was the cause of present and predicted future oversupply. They also questioned the premise that oversupply itself necessarily increases the threat of diversion to illicit markets. Furthermore, they pointed out, Australia, France, Turkey and India had already pledged to reduce acreage, thereby reducing the potential of future oversupply. The projections compiled by the INCB were also questioned and the spectre of future shortages was raised. The U.S. was cautioned not to assume that nontraditional suppliers would be ready to meet emergency shortages in the absence of an assured long-term U.S. market.

It was also suggested that the proposed rule could be anti-competitive and inflationary, adversely affecting American consumers. But the DEA pointed out that there was already a

* As evidenced by its recent decision on the domestic cultivation of *Papaver bracteatum* (42 Fed. Reg. 28560), the U.S. pledged to support the traditional suppliers rather than authorize its own domestic production of such narcotic raw materials.

Memorandum, "80-20" Rule
Page 10
August 1989

closed regulatory system, and that such a limitation was justified when balanced against the need to prevent diversion into the illicit drug traffic.

Alternative proposals were advanced to retain access to the U.S. import market for the nontraditional nations. They included redefining "traditional suppliers" to cover countries that exported narcotic raw materials lawfully cultivated during the ten years before 1979; reserving 30% of the import market for countries other than India and Turkey; or amending the exception provision to insure continued availability of sufficient supplies at reasonable prices. DEA expressed a willingness to receive more information about these alternatives in response to the proposed rule.

D. Notice of Hearing

The nontraditional suppliers were plainly dissatisfied with the proposed rule, notwithstanding the limited exception provision. Francopia, representing the French interests, and Tasmania, the Australian state where the poppies are cultivated, as well Senator Birch Bayh, requested a hearing on the proposal. The DEA, in response to these requests and to written comments, scheduled a hearing in September 1980, before Administrative Law Judge (ALJ) Francis L. Young. 45 Fed. Reg. 49295 (July 24, 1980). The subject matter of the hearing was the feasibility of the proposed rule and two additional questions:

1. Whether the U.S., consistent with its international obligations in general, and with CND Resolution 471, can allocate a fixed portion of the narcotic raw materials it imports to the "traditional" producing countries, and the remainder to "non-traditional" sources; and,
2. If allocation is permissible, what proportions are appropriate.

E. Report by the Administrative Law Judge

Following the September 1980 hearing, the ALJ issued a report, summarizing the written and oral submissions made in response to the proposed rule, and making recommendations on the rule to the DEA Administrator.

Memorandum, "80-20" Rule
 Page 11
 August 1989

1. Comments and Objections after Publication of the Notice of Hearing

Once again, the State Department supported the DEA proposal which did not reserve an import quota for nontraditional suppliers; in fact, the State Department expressly opposed the concept of a quota. So, too, did the traditional suppliers. They claimed it would be contrary to U.N. Resolutions 471 and 497 to allow imports from nontraditional suppliers, and that it was inconsistent with the 1961 Single Convention on Narcotic Drugs. Furthermore, it was contrary to U.S. law in that the DEA did not have the authority to promulgate such a rule. They contended that any such rule would be unconstitutional, arbitrary, capricious and an abuse of discretion. Accordingly, they, too, supported the DEA proposal.

The proposed rule again met with objections from the nontraditional suppliers, however. France and Hungary took issue with the definition of "traditional suppliers," contending that as longtime suppliers of CPS, they should have the same import rights as India, Turkey and Yugoslavia.¹⁰

Others argued that it was not in best interest of the U.S. to rely on India and Turkey because of supply uncertainties owing to political as well as climatic conditions. Furthermore, they again pointed out, the United States could not rely on other nontraditional countries to provide alternative sources whenever needed. For example, the lack of an assured long-term market would encourage a decline in Australian production. Hence, reliance on the traditional countries could precipitate a shortage rather than simply control overproduction. It was also suggested that, by guaranteeing a market to India and Turkey, the United States would lose economic leverage over them to assure strong controls against diversion from their crops.

Again, the accuracy of the oversupply estimates from INCB were questioned, since the emphasis in the figures was on

¹⁰ Hungary stated it has been producing alkaloids from poppy straw since 1930, and exporting since 1942. France stated it has worked on the poppy straw process since 1923, and has exported alkaloids commercially since 1945.

Memorandum, "80-20" Rule
Page 12
August 1989

capacity rather than production.¹¹ Thus, commentators noted, the emphasis on preventing oversupply may be misplaced. They also pointed out again that surpluses do not necessarily increase the risk of diversion.

Alternative proposals were offered by supporters of a quota. They varied from a ratio for traditional versus nontraditional suppliers ranging from 70-30 to 80-20. Some commentators suggested that the nontraditional suppliers should have to compete with the traditional suppliers for their share of the U.S. market. Another suggestion was to give a preference to CPS imports from nontraditional countries which contained a high percentage of thebaine.

2. Discussion of Resolutions 471 and 497

The ALJ disagreed with Australia's position that the Resolutions were intended to limit production in both traditional as well as nontraditional countries. Upon reviewing a verbatim transcript of the adoption of Resolution 497, a copy of which was attached to his Report, the ALJ found that the record did not support Australia's contention. The initial resolution as introduced by Turkey and India is the Resolution that was adopted. The restrictions on production were not to apply to the traditional suppliers. Furthermore, the ALJ found that DEA's proposed policy and regulatory revisions were consistent with these two Resolutions.

3. Analysis of DEA's Authority

a. The Statute

The ALJ found statutory authority for both the proposed rule, and for a quota. The United States has expressly recognized the dangers of illicit drugs and has delegated broad powers to the Attorney General under the Controlled Substances Act of 1970 to deal with the menace. The Attorney General, in turn, has statutory authority to delegate its rulemaking power to the DEA. Moreover, restraining proliferation of overseas raw materials production is related to the purpose of the Act. The DEA can restrict or channel imports to prevent diversion of licit

¹¹ For example, Netherlands had produced alkaloids from straw produced in Turkey. This straw will no longer be available as Turkey intends to use its full supply once its CPS plant is operational.

Memorandum, "80-20" Rule
 Page 13
 August 1989

substances. In 1970, opium gum was the sole significant source of narcotic alkaloids. With the advent of poppy straw and CPS, the rules may be revised to adjust to this situation.

b. International Trade Policy of the United States

The ALJ also found that both the proposed rule and the adoption of a quota would be permissible under existing international trade policies. However, contrary to the views of the State Department, the Department of Commerce and the USTR pointed out the potential adverse effects of the proposed rule on Hungary, France and Australia. These nontraditional suppliers had adequate controls against diversion, but would be substantially excluded from the United States market unless a quota protected their imports. Both Commerce and the USTR also believed that the rule raised problems under the General Agreement on Tariffs and Trade. They recommended a quota system based on a "recent representative period" whereby the bulk of the U.S. market would go to traditional suppliers, with Hungary, France and Australia sharing the remainder.

4. ALJ's View on the Likely Effects of the Proposed Rule

The ALJ's analysis of the consequences of exclusive United States reliance on India and Turkey for narcotic raw materials under the DEA's proposed rule led him to recommend instead the adoption of an import quota system. He enumerated the disadvantages of exclusive reliance on these two countries as follows.

- a. Uncertainty of supplies. India, Turkey and Yugoslavia, all in the same hemisphere, have non-irrigated land. They depend on adequate rainfall. In addition to climatic instability, they are volatile politically.
- b. Loss of leverage. Reliance on two suppliers would result in a loss of leverage to assure that these countries maintained strong controls against diversion. If the United States had no alternative suppliers, it might well have to accept inadequate levels of control to assure supplies.
- c. Prices. Reliance on the two countries increases the risk of unreasonable prices. This is particularly true in light of the anticipated increased demand, due to the availability of medical insurance and the essential nature of the commodity.

Memorandum, "80-20" Rule
Page 14
August 1989

- d. Temporary shortages. The exception provision would not solve the problem of temporary shortages. Although the exemption would allow CPS imports from Australia, France, Hungary and Poland, the exemption procedure contemplated was time-consuming, cumbersome and lacking clear standards. An evidentiary hearing would be required to determine if supply was "adequate" or prices were "unreasonable" before the exemption would be implemented. Therefore, faced with an uncertain and sporadic U.S. market, producers, in particular Tasmania, would have no incentive to remain in the business.
- e. Risk of diversion. The proposed rule might increase the risk of diversion by artificially increasing the demands upon Turkey and India, in view of the U.S. commitment to purchase all their supply. The effect of this rule could be to stimulate rather than curtail oversupply, with the U.S. as a guaranteed market. If synthetics were then developed and substituted for imports from these countries, the incentive for diversion would increase. These countries have large stocks which they are trying to reduce. While the evidence suggests that they have adequate controls, there is a speculative threat of diversion.
- f. Emergency needs. There is a long lead time required for the United States to cultivate its own sources. Existing synthetics cannot be relied on as substitutes for narcotics. It is not known if such substitutes might ultimately eliminate the need for natural raw materials, or if the natural products will prove to be the safest, least expensive analgesics.
- g. International cooperation. The State Department expressed some fear that a quota system would result in a loss of cooperation from India and Turkey in controlling illicit drugs. The ALJ concluded that this fear was not well-founded. As signatories to the Single Convention, Turkey and India would abide by their requirements and the threat of international lawlessness was not a basis on which to make policy.

Memorandum, "80-20" Rule
Page 15
August 1989

5. Maintaining Australian Supply Availability

The ALJ pointed out that a quota system would allow CPS imports from Australia. He saw this as an advantage to the U.S. because of Australia's political stability and its location in the southern hemisphere. Additionally, production in Tasmania is less dependent on favorable weather conditions because of the availability of sophisticated irrigation methods.

The ALJ also noted that Australia has stringent controls against diversion and that use of the CPS process reduced the likelihood of diversion of gum opium from the fields. Moreover, the type of poppy cultivated, and the climatic conditions in Tasmania, are unsuited to the production of gum opium. Finally, cultivation is located on the remote and unpopulated island of Tasmania where it would be difficult for drug traffickers to operate.

Relying on Australian regulation, as well as the capacity of the two producers there, the ALJ concluded that the maximum amount of Australian CPS likely to be available to the U.S. market would not exceed 20 percent of domestic needs. Without some assurance of a market in the U.S., he predicted that one of the producers would discontinue cultivation, and the other would scale back production.

6. Conclusion

The ALJ recommended that DEA formulate a rule providing for the allocation of the majority of narcotic raw material imports to the "traditional" producer countries, and the remainder to "nontraditional" suppliers. However, he found that the record did not provide a basis for recommending a particular ratio.

The DEA staff attorney recommended 80 percent for the "more traditional" countries, and 20 percent for the "less traditional," with a preference for materials containing the greatest amount of thebaine. The USTR proposed a global quota based on a "recent representative period" and a redefinition of "traditional" suppliers. Francopia, the French producer of CPS, argued for a 70-30 allocation, based on the then-current export market shares of India, Turkey and Yugoslavia. The ALJ considered these reasonable solutions for the DEA, but declined to adopt any one of them.

Memorandum, "80-20" Rule
Page 16
August 1989

VI. SUMMARY

The ALJ found the proposed rule, when modified and combined with a quota system, both legally feasible and desirable from a policy perspective. A few months after the ALJ Report was released, the 80-20 rule was adopted.

The 80-20 quota favors the traditional suppliers, yet allows twenty percent of the narcotic raw material imports to originate with nontraditional producers. This system retains the political, regulatory and economic advantages of primary reliance upon Indian opium gum and Turkish and Yugoslavian CPS imports. To that extent, it is responsive to the position of the State Department that support of the traditional suppliers is essential to international cooperation in controlling narcotic drugs and is consistent with existing international treaties. At the same time, the use of a quota system has opened up the U.S. market to competition by allowing some CPS imports from nontraditional countries.

This quota system has been in effect since 1981. There have been no developments in narcotic raw material regulation, production, processing or distribution since that time to alter the policy or legal considerations which led to the adoption of the 80-20 rule.

Memorandum, "80-20" Rule
 Page 17
 August 1989

CHRONOLOGY

1961	Single Convention on Narcotic Drugs
1970	Drug Abuse and Prevention Control Act of 1970, Controlled Substances Act of 1970 and Controlled Substance Import and Export Act
Feb. 1979	U.N. Commission on Narcotic Drugs (CND) adoption of Resolution 471
June 12, 1979	Advanced Notice of Proposed Rulemaking (44 Fed. Reg. 33695) "Proposed Limitations on Imports of Narcotic Raw Materials"
Feb. 12, 1980	Notice of Proposed Rulemaking (45 Fed. Reg. 9289) "Proposed Limitations on Imports of Narcotic Raw Materials"
Feb. 19, 1980	U.N. CND adoption of Resolution 497
April 30, 1980	U.N. Economic and Social Council adoption of Resolution 497
July 24, 1980	Notice of Hearing (45 Fed. Reg. 49295)
Sept. 9, 1980	Hearing commences
Jan. 16, 1981	Report to DEA Administrator by ALJ
July 29, 1981	Final Rule (46 Fed. Reg. 41775) "Limitations on Imports of Narcotic Raw Materials"
Nov. 18, 1988	Anti-Drug Abuse Act of 1988

**APPENDIX 5.—REPORT TO CONGRESS: LICIT OPIUM REVIEW, PREPARED
BY THE DEPARTMENT OF STATE, BUREAU OF INTERNATIONAL NAR-
COTICS MATTERS, AND THE DEPARTMENT OF JUSTICE, DRUG
ENFORCEMENT ADMINISTRATION**

TABLE OF CONTENTS

SECTION	PAGE
EXECUTIVE SUMMARY	1
INTRODUCTION	4
MEDICAL USE AND ECONOMIC CONSIDERATIONS	6
I. Role of Papaver somniferum L. in modern medicine	6
II. Role of Papaver somniferum L. in United States economics	10
III. Role of Papaver somniferum L. in the illicit drug traffic	13
THE "80-20 RULE" -- 1312.13 CFR	16
I. Historical Basis of Policy	16
II. The Opium Shortage and the "80-20 Rule"	18
III. Experience Under the Rule	20
IV. Possible Modifications	22
V. Recommendations	23
COUNTRY REPORTS:	25
Turkey	25
Australia	29
India	33
U.S. INDUSTRY	41
FINDINGS AND RECOMMENDATIONS	43
APPENDIX: Drugs derived from Papaver somniferum L. and Papaver bracteatum L.	47

EXECUTIVE SUMMARY

The Anti-Drug Abuse Act of 1988 (Section 4307, P.L. 100-690) mandated a review and report to Congress "to determine --

"1) the current and reserve international needs for opium-derived pharmaceutical and chemical products, and the relative capabilities for meeting those needs through the opium gum process and the concentrated poppy straw method of production;

"2) whether the United States should continue to rely on a single foreign country for all its licit opium gum;

"3) whether it should be United States policy to encourage all countries which produce licit opium to use the concentrated poppy straw method of production; and

"4) what options are available, consistent with treaties to which the United States is a party, to reduce United States reliance on licit opium gum from foreign sources."

This review was conducted jointly by the Bureau of International Narcotic Matters of the Department of State, the Drug Enforcement Administration of the Department of Justice, and the Food and Drug Administration of the Department of Health and Human Services.

In developing this report, representatives of the reviewing organizations made on-site visits to India, Turkey, and Australia. These nations are the principal suppliers for the United States pharmaceutical industry's production of licit opium derivatives.

In addition, the three American importers/processors were extensively interviewed and were invited to provide written statements in response to specific questions submitted by the review team.

The following findings and recommendations resulted from this review:

1) Current procedures, based upon the "80-20 Rule," have provided the United States with reliable sources for licit narcotic raw material (opium) for its pharmaceutical industry. Future needs can also be adequately met under this process.

2) Unless the United States permits the growth of opium poppies within its borders, which the government has consistently opposed, the only source of licit opium is from foreign sources. The United States government supports the continuation of its program of reliance on such sources.

3) Because the licit American pharmaceutical industry can utilize both concentrate of poppy straw and opium gum in its manufacturing processes, to have only one supplier of opium gum is not detrimental to the industry. The major difference between CPS and opium gum is the lack of the alkaloid noscapine in CPS. Since noscapine has no current medical use in the United States and has value solely to the extent that it can be exported (mainly to Japan), U.S. medical needs would not be affected by its absence. For this, and other reasons, the American industry generally prefers to utilize poppy straw. Thus, the reliance on opium gum production by India may hurt that producing nation's sales program in the future. Therefore, it would be to India's benefit to convert at least a part of its production to the poppy straw method so that it could remain competitive with other major licit producers.

4) It is recommended that the "80-20 Rule" be maintained in its present form for an additional three years. This affirmation should not, however, translate to a full endorsement of the status quo.

A) During this period, the United States should continue to support India as a traditional supplier of the licit raw material, subject to the conditions of the Rule, while entering into negotiations with India to correct imbalances caused in part by the operation of the Rule.

These negotiations should encourage India to take action to reduce the opportunity for diversion from the field by expansion of enforcement and inspection control. The negotiations should also seek to assist

-3-

India in reducing its opium stockpile and to bring its production into line with market conditions. India should also be encouraged to consider a partial conversion to the concentrate of poppy straw process.

B The United States should continue to support Turkey as a traditional supplier of the licit raw material subject to the conditions of the "80-20 Rule." However, the United States should actively encourage Turkey to consider production of alternative products as a means of utilizing the full capacity of its processing factory rather than to expand the areas of poppy cultivation.

5) At the end of this three-year period, the "80-20 Rule" should be reexamined. Continuing or restructuring the Rule should be reevaluated in part on the basis of the responses and actions of Turkey and India, the major licit opium producing nations, to the above.

6) The United States should provide direct and indirect assistance, to the extent available, to aid India and Turkey in meeting the stated objectives.

7) In recognition of the favored position granted to the small group of licit opium suppliers, the United States should continue to be sensitive to any formal or informal agreements which seek to establish price levels above customary competitive levels. Such events would require immediate revision of the existing Rule.

INTRODUCTION

The Anti-Drug Abuse Act of 1988 (Section 4307, P.L. 100-690) mandated a review and report to Congress "to determine --

"1) the current and reserve international needs for opium-derived pharmaceutical and chemical products, and the relative capabilities for meeting those needs through the opium gum process and the concentrated poppy straw method of production;

"2) whether the United States should continue to rely on a single foreign country for all its licit opium gum;

"3) whether it should be United States policy to encourage all countries which produce licit opium to use the concentrated poppy straw method of production; and

"4) what options are available, consistent with treaties to which the United States is a party, to reduce United States reliance on licit opium gum from foreign sources."

This review and report was a joint project of the Bureau of International Narcotics Matters of the the Department of State, the Drug Enforcement Administration of the Department of Justice, and peripherally, the Food and Drug Administration of the Department of Health and Human Services.

The review focused on several main issues of concern:

1) The 80-20 Rule: This Rule, in effect since 1981, stipulates that 80% of the U.S. market for licit narcotic raw material be reserved for the "traditional" suppliers: India and Turkey. The remaining 20% of the market is open to Australia, France, Hungary, Poland, and Yugoslavia.

This policy was designed to adhere to the traditional U.S. interest of limiting the number of licit producing nations. It recognized the unique role of the traditional supply countries while at the same time acknowledging those countries which assisted the United States during the opium shortage of the mid-1970's. Key questions for this review include whether this Rule should be maintained, modified or eliminated.

2) World oversupply of Licit Opium Raw Material: World production and demand for licit opiates have been in approximate balance in recent years. Excess stocks,

however, remain high. This situation invites attempts at diversion. Although there is virtually unanimous international agreement that stock levels must be brought down, there is no agreement as to how this should be done.

3) Indian stockpile and diversion: For a number of reasons which are discussed in the body of this report, India has not been able to significantly reduce its stockpile of opium gum which now totals approximately 2,000 metric tons. Because intelligence reports indicate that raw opium is being diverted from licit production at the farmgate, this large stockpile is all the more worrying. Therefore, this report considers the important issue of reducing the Indian stockpile and curtailing diversion from the fields.

4) Excess capacity in Turkey: Turkish production is limited to concentrate of poppy straw which is processed in its alkaloid plant in Bolvadin. Turkey is in the process of markedly expanding its licensed areas for opium poppy cultivation and is reported to be planning the opening of a second production line in its Bolvadin plant. This action is being taken despite the current market conditions which show neither a need for the increased production nor a world-wide ability to readily absorb it. The report will, therefore, examine the implications of this excess capacity.

5) The need for U.S. manufacturers to have access to reasonably priced and reliable sources of licit opium: Although control has been the driving force behind the traditional U.S. licit opium policy, the needs of the pharmaceutical industry must also be considered. This report will therefore also attempt to determine whether or not current policy has provided U.S. manufacturers with access to needed raw materials at fair prices.

MEDICAL USE AND ECONOMIC CONSIDERATIONS

The opium poppy, Papaver somniferum L., has been cultivated for medicinal purposes for centuries. Today, the opium poppy is grown for three principal reasons:

1) to provide poppy seeds which are frequently added to baked goods and from which is extracted poppy seed oil used in cooking and in the manufacture of paints, varnishes and soaps;

2) as a source of substances that have useful medicinal properties of their own and/or are used to make other drugs used in modern medicine; and

3) to supply opium to the illicit drug market for the purpose of making illicit drugs, particularly heroin.

This report provides a brief review of the role of Papaver somniferum L. in modern medicine, in the licit United States drug market and in the illicit drug traffic.

I. Role of Papaver somniferum L. in modern medicine

Papaver somniferum L. is the source of opium and of several alkaloids used in modern medicine. Opium gum is the viscous latex obtained after making cuts in the unripe capsule of the poppy plant. It contains as many as 20 different alkaloids, including morphine, codeine, and thebaine which, collectively, comprise 20-25 percent of the mass of opium. Table I shows the percentage composition of the most abundant alkaloids found in opium.

Table 1: Predominant Alkaloids Found in Opium.*

<u>Alkaloid</u>	<u>Percent by Weight</u>
Morphine	10 - 16
Noscapine	4 - 8
Codeine	0.8 - 2.5

* Obtained from Merck Index, 10th Edition

An additional source of such alkaloids is poppy straw which is a bulky raw material generally consisting of the unincised, dried, ripened capsules which has a small portion of the stem of the opium poppy attached. According to available statistics from the International Narcotics Control Board (INCB), countries that harvested poppy straw in 1987 included Australia, France, Spain and Turkey. Although poppy straw contains some, if not all, of the same alkaloids found in opium, data on the actual percentage composition of poppy straw harvested in these countries is not available.

Using techniques such as the Kabey process, poppy alkaloids can be isolated from the poppy straw. According to INCB statistics for 1987, morphine was manufactured directly from poppy straw in Czechoslovakia, Hungary, Poland, Romania, Turkey and the Netherlands.

For purposes of international trade, poppy straw is usually processed to concentrate one or more of the alkaloids. This processed material is known as "concentrate of poppy straw" or CPS. According to INCB statistics, the major countries which manufactured CPS in 1987 were Australia, Turkey, France, Spain, the Netherlands and Denmark.

The alkaloid composition of CPS differs depending on the country of manufacture. CPS manufactured in Australia and France contains primarily morphine with, to a lesser extent, thebaine and codeine. CPS from Turkey contains morphine and minimal codeine but no thebaine. Noscapine is not found in CPS exported from Turkey, France or Australia. Information on the alkaloid content of CPS manufactured in other countries is not available. These differences in alkaloid content may reflect differences in alkaloid extraction techniques or in the alkaloid composition of Papaver somniferum L. Currently CPS is prepared primarily to provide a high concentration of morphine. As such, CPS is a commercial source of morphine and to a much lesser extent codeine and thebaine, but not noscapine.

Opium is used for medicinal purposes in many countries including the United States, where more than a dozen preparations of opium usually in combination with other substances are available for the treatment of several medical disorders. In many of these preparations, opium is the principal active ingredient. One well known combination product containing camphor and opium is paregoric which is used as an antidiarrheal agent. The effects of opium are, in turn, due primarily to the actions of morphine and to a lesser extent to codeine, papaverine and noscapine which are present in the opium. Thus, opium produces analgesic, anti-tussive, sedative and antidiarrheal effects.

The various preparations containing opium are used in the United States, as well as other countries, for the treatment of moderate to severe pain, diarrhea, cough and colicky cramps. The aggregate production quota for powdered opium reflects the level of use of opium-containing products in the United States. The quota for opium has declined from 2,400 kilograms in 1979 to 1,500 kilograms in 1988, thus indicating a 35 percent decrease in the use of opium over the ten year period.

Opium is extensively used as a source for the extraction of alkaloids produced by Papaver somniferum L. Figure I in the Appendix shows some of the more important opium-derived alkaloids and some of the drugs which are synthesized from them.

Important alkaloids obtained from opium include noscapine, morphine, codeine, thebaine and papaverine. It should be emphasized that opium is the only source of noscapine. The toxic alkaloid thebaine is important in the synthesis of certain narcotics including codeine, oxycodone, oxymorphone and etorphine. Thebaine is also used to make the narcotic antagonists, naltrexone and naloxone and the mixed agonist-antagonists, buprenorphine and nalbuphine. Morphine is used to synthesize heroin, ethylmorphine, codeine and hydromorphone. Most of the morphine produced in the United States is used to synthesize codeine. In fact, this synthetic process is the principal method for producing codeine. Hydrocodone and dihydrocodeine are synthesized from codeine.

As shown in Figure I, (see Appendix) Papaver bracteatum L. is an alternative source for thebaine and thus thebaine-derived drugs. Thebaine can be obtained from the latex of incised capsules of the unripe bracteatum plant. This latex gum is more fluid than that obtained from somniferum and is handled somewhat differently. A concentrate of bracteatum straw would also contain thebaine. Papaver bracteatum L. produces little or no morphine or codeine.

Most of the alkaloids derived from Papaver Somniferum L. are used in clinical medicine in the United States and many other countries:

-- Morphine and codeine have analgesic, anti-tussive and sedative effects. They are used in a variety of preparations to treat mild to severe pain resulting from various disorders. Morphine and codeine are considered by the World Health Organization to be "essential drugs" that should be available in all countries for the treatment of severe pain, such as that associated with cancer. Currently, there is much concern in the medical profession that in many countries these drugs are not being used in adequate quantities to treat individuals suffering from

severe pain. It seems likely that in the future the use of morphine, codeine and many other narcotics for the treatment of severe pain will increase in many countries. Morphine is used as preoperative medication and as a primary anesthetic. Codeine is marketed in various formulations for the treatment of pain and cough.

-- There are no therapeutic indications for the use of thebaine.

-- Papaverine and noscapine are isoquinoline alkaloids and are specifically excluded from the schedules of the Controlled Substances Act (CSA). Papaverine is a nonspecific smooth muscle relaxant which is chemically and pharmacologically unrelated to morphine or codeine. Although there is little evidence to support its clinical use, papaverine is found in some preparations which are used to treat cough or conditions associated with arterial spasm and myocardial ischemia. Noscapine has anti-tussive activity but essentially no analgesic or sedative effects. It is used primarily as a cough suppressant. Noscapine preparations are not used in the United States but are available in Europe and Japan where they are used as an alternative to codeine to suppress cough. Noscapine is manufactured for export only by Mallinckrodt, Inc. and McNeil Laboratories, Inc.

Many drugs synthesized from opium alkaloids are important therapeutic agents. The narcotic agonists (i.e. dihydrocodeine, hydrocodone, heroin, ethylmorphine, hydromorphone, oxycodone and oxymorphone) and mixed agonist-antagonist (i.e., nalbuphine and buprenorphine) have analgesic activity and are used to treat mild to severe pain. Heroin, a powerful analgesic drug, is not currently available as a licit drug in the United States. The narcotic antagonists naloxone and naltrexone block many of the effects of narcotics. They are used in the treatment of narcotic-induced toxicity and in the diagnosis of narcotic physical dependence. Etorphine is used exclusively for immobilizing animals.

From the standpoint of medical utility, there are alternative drugs available to treat most disorders that are currently treated by substances derived from Papaver somniferum L. Several synthetic analgesics such as fentanyl and its analogs, meperidine, alphaprodine and methadone are effective in the treatment of mild to severe pain. Drugs such as diphenoxylate, difenoxin and loperamide may be used in place of opium to treat diarrhea. Dextromethorphan and levopropoxyphene are employed as anti-tussive agents. Sedative or anti-anxiety drugs are as effective as narcotic drugs for preanesthetic medication.

-10-

There are no drugs available to replace the narcotic antagonists for the treatment of narcotic overdose. It should be noted that Papaver bracteatum L. may be cultivated in place of Papaver somniferum L. to provide a source of thebaine which, in turn, would allow for the synthesis of narcotic antagonists. Mallinckrodt, Inc. has a patented process for the production of naloxone, naltrexone and nalbuphine from morphine. Other drugs such as oxycodone and buprenorphine must, however, still be made from thebaine.

II. Role of Papaver somniferum L. in United States economics

It is unlawful to import into the United States any Schedule I or II narcotic drug except the narcotic raw materials opium, poppy straw and CPS. Imported CPS contains not more than 80 percent morphine alkaloid by weight; CPS with a higher percentage of morphine alkaloid is considered to be crude morphine.

The importation of these raw materials must conform to the "80-20 Rule" in that at least 80 percent of the imported raw material must come from the traditional cultivating nations, India and Turkey. The remaining 20 percent may be imported from non-traditional countries such as Australia, France, Hungary, Poland and Yugoslavia.

The licit raw materials actually imported into the United States are opium and concentrate of poppy straw, or CPS. Poppy straw, which was used briefly during the "opium shortage" of the mid-seventies, is no longer imported.

There are currently three United States companies registered with the Drug Enforcement Administration (DEA) to import narcotic raw materials. These companies are Mallinckrodt, Inc. (St. Louis, Missouri), S. B. Penick and Company (Newark, New Jersey) and a subsidiary of Johnson & Johnson, McNeil Laboratories, Inc. (Fort Washington, Pennsylvania). Collectively, these companies provide opium and some of the alkaloids of Papaver somniferum L., including morphine, for the domestic United States drug market and for export.

India is the only nation that exports opium gum to the United States. In 1988 the United States imported approximately 207,350 kilograms of opium gum which contained approximately 20,735 kilograms of anhydrous morphine alkaloid (AMA). In 1988, the world price was \$315 per kilogram of AMA which would extrapolate out to a total cost of \$6,531,525. This, however, represents the upper limit of cost and not the actual total amount paid by the three companies, since each company

-11-

negotiates its own price with the exporting country. As shown in Table 2, during the period 1985 to 1988, there has been a gradual reduction in the quantity of opium imported by the United States. This reduction in opium importation reflects an increase in the use of CPS for alkaloid extraction due to a decreased need for certain alkaloids of opium gum such as noscapine.

Table 2: Importation of Indian Opium from 1985 through 1988.

<u>Year</u>	<u>Kilograms Imported</u>
1985	398,087
1986	308,340
1987	240,553
1988	207,350

Table 3 provides data on the amount and origin of CPS imported into the United States from 1985 through 1988. In 1988, 53,508 kilograms of CPS were imported by the United States. Of that amount, 69 percent was imported from Turkey, 21 percent from Australia and 10 percent from France. Assuming that the CPS was 80 percent AMA, then the 53,508 kilograms of CPS contained approximately 42,806 of AMA. Given that the 1988 world price of CPS was \$175 per kilogram of AMA, then the total cost for all imported CPS for 1988 would theoretically equal \$7,491,050. This represents the upper limit, but not the actual cost, of the imported CPS.

Table 3: Sources of CPS imported from 1985 through 1988.

<u>Year</u>	<u>Kilograms</u>	<u>Percent of Total</u>	<u>Imports by Country</u>		
			<u>Australia</u>	<u>France</u>	<u>Turkey</u>
1985	12,524	53			47
1986	12,305	56		23	21
1987	51,708	26		14	60
1988	53,508	21		10	69

Data from Table 3 shows a greater than fourfold increase in the importation of CPS since 1985. In 1985 approximately equal amounts of CPS were imported from Turkey and Australia. In 1987 and 1988 the largest percentage of CPS imports came from Turkey.

Opium and CPS are used by the three importing companies to produce morphine, codeine, thebaine, noscapine and papaverine. Data on the actual percentages of total manufactured morphine, codeine and thebaine produced from either CPS, opium or morphine is given in Tables 4 and 5.

Table 4: Percentages of Morphine and Thebaine Manufactured from either CPS or Opium Gum between 1982 and 1987.

Year	<u>% of Morphine Produced from</u>		<u>% Thebaine Produced from</u>	
	CPS	Opium Gum	CPS	Opium Gum
1982	30	70	17	83
1983	36	64	4	96
1984	23	77	2	98
1985	19	81	4	96
1986	11	89	-	100
1987	58	42	8	92

For the period 1982 through 1986, an average of 76 percent of manufactured morphine was obtained from opium gum. The remaining morphine was manufactured from CPS. In 1987, the percentage (58%) of morphine manufactured from CPS actually exceeded the percentage (42%) obtained from opium gum.

Table 5: Percentage of Total Manufactured Codeine Produced from Morphine, Opium and CPS during the Years 1982 to 1987.

Year	Morphine	<u>% of Codeine Produced from</u>	
		Opium	CPS
1982	74	18	1
1983	84	15	1
1984	81	19	-
1985	93	7	-
1986	49	50	1
1987	54	18.5	27.5

During the period 1982 to 1985, the average annual production of codeine in the U.S. was 53,341 kilograms. Of that amount, the mean percentage manufactured from morphine was 84 percent, from opium 15 percent and from CPS approximately 1 percent. In 1986 and 1987, the quantities of codeine manufactured were 54,797 and 58,147 kilograms, respectively. In 1986, the percentage of manufactured codeine obtained from morphine, opium and CPS were 49 percent, 50 percent and 1 percent, respectively. In 1987, the percentage of codeine obtained from CPS jumped to 27.5 percent. The remaining codeine was manufactured from morphine (54%) and opium (18.5%).

From 1982 through 1987, the average annual production of thebaine was 4,163.8 kilograms. The largest amount (5,022 kilograms) was produced in 1984, after which there was a progressive decline to 3,239 kilograms in 1987. During this six year time period, an average of 94 percent of the manufactured thebaine was extracted from opium. The remaining 6 percent was obtained from CPS.

The United States is the world's leading importer and consumer of licitly produced opium gum. According to INCB statistics, the United States is the largest importer of Indian opium gum. During the period 1982 to 1984, approximately 45 percent of the annual exports of Indian opium gum were sent to the United States. For 1985 and 1986, the approximate percentage of annual licit opium gum exports from India to the United States was 50-54 percent. In 1987, the countries importing Indian opium gum included the United States (36%), the Union of Soviet Socialist Republics (29%), the United Kingdom (18%), Japan (12%), France (4%) and the Federal Republic of Germany (.4%). It should be noted that, according to INCB statistics, Japan and the People's Republic of China also manufactured opium for domestic medical and scientific purposes. According to INCB statistics for the period 1982 - 1987, the United States annually utilized more licit opium than any other country. Other countries that have utilized significant quantities of licit Indian opium gum include the Union of Soviet Socialist Republics, the United Kingdom, Japan, France and Italy.

According to INCB statistics for 1987, the United States was the leading importer of CPS. In 1987, the United States imported approximately 45-53 percent of the total CPS exported. Other countries importing significant quantities of CPS in 1987 were the United Kingdom (27-32%), Norway (4-5%), Denmark (2-3%), Yugoslavia, Italy and Belgium. In 1986, the United States ranked fourth behind the United Kingdom, Norway and Denmark in the amount of CPS imported.

III. Role of *Papaver somniferum* L. in the illicit drug traffic.

Papaver somniferum L. is extensively grown to supply opium for the illicit drug traffic. Currently, there is no evidence that poppy straw or CPS is a source of illicit narcotics. Illicit opium is either used as such or is used to extract morphine which is converted to heroin.

The National Narcotics Intelligence Consumers Committee (NNICC) reported that for 1987, the three major illicit opium producing regions are Mexico, Southwest Asia and Southeast Asia. These regions produce sufficient quantities of opium for their domestic needs and for exporting to other countries. The Southwest Asian region includes Afghanistan, Iran and Pakistan; the Southeast Asian region includes Myanmar (Burma), Laos and Thailand. Heroin from these two regions derives from opium produced within each region, e.g., Southwest Asian heroin is produced from Southwest Asian opium. Mexican heroin is usually made from morphine derived from Mexican opium and processed in

-14-

Mexico. Table 6 shows the annual opium production in metric tons for the three regions from 1984 through 1987. The data clearly show that the annual production of illicit opium has increased in all three regions since 1984.

Table 6: Annual Production of Illicit Mexican, Southeast Asian and Southwest Asian Opium between 1984 and 1987.*

Region	<u>Metric Tons of Opium</u>			
	1984	1985	1986	1987
Mexico	21	28.4	20-40	45-55
Southeast Asia	815	625	820-1415	1095-1575
Southwest Asia	580-830	640-970	840-1360	735-1360

* data from the 1987 NNICC Report.

India is considered to be a net importer of illicit opium. This reflects the large domestic use of opium and heroin within India. The amounts of illicit opium produced and exported from India are not known. There is also no accurate data on the amount of diversion of licit opium in India. Considering the amount of illicit opium produced worldwide, it is unlikely that opium diverted from legitimate opium supplies in India contributes significantly to the amount of opium or heroin found in the illicit narcotic traffic, including that coming into the United States.

Table 7: Geographical Origins of Heroin Exhibits Analyzed under the Heroin Signature Program between 1985 and 1987.

Year	<u>No. of Exhibits</u>	<u>Percent of Total Exhibits</u>		
		Mexico	Southeast Asia	Southwest Asia
1985	405	39	14	47
1986*	294	42	22	36
1987*	315	42	25	33

* Incomplete Data

According to the 1987 NNICC Report, heroin and illicit opium entering the United States comes from Mexico, Southeast Asia and Southwest Asia. Evidence in support of this comes from the Heroin Signature Program. In this program, chemical analysis is used to identify and quantify characteristics and secondary constituents of selected heroin samples. From this data, heroin exhibits are classified according to the process by which they are manufactured, which in turn permits the association of exhibits with geographic areas. The exhibits are part of random samples purchased or seized from locations in the United States including ports of entry.

Table 7 provides data obtained from the Heroin Signature Program for the period 1985 to 1987. Data obtained from the Heroin Signature Program provides evidence that heroin reaching the United States originates in Mexico, Southeast Asia and Southwest Asia. Due to inherent problems of sampling, it is not possible to extrapolate to provide accurate figures on what percentage of the heroin reaching the United States actually originates in each of the three geographical regions.

THE "80-20 RULE" -- 1312.13 CFR

The United States is the world's largest single purchaser and consumer of licit opium raw materials, averaging about 60 tons of anhydrous morphine alkaloid (AMA) annually, or about 43% of the world market for such material. In spite of this considerable national need, the United States has elected to rely entirely upon foreign sources for its supply. This policy may have evolved originally out of economic factors, but is now sustained only by subordination of economic factors to national narcotic control policy.

I. Historical Basis of Policy

During the latter half of the 19th century, Papaver somniferum was cultivated for opium production in several regions of the United States. The reasons for its abandonment, which occurred at some time during the close of the century, are not documented but probably relate to the cheaper cost of labor available in such countries as China and India and increasing public concern for tighter control. U.S. industry in this regard seems to have followed the classic pattern of importation of cheap, crude raw material to which profit and value were added through the application of domestic industrial technology.

With the passage of the Harrison Narcotic Act in 1914, and the creation of the Federal Bureau of Narcotics in 1930, national policy on the issue of domestic cultivation of Papaver s. came under the control of the Federal Drug control authorities where it has remained. In 1942, at the request of the U.S. Commissioner of Narcotics, Harry J. Anslinger, Congress passed the Opium Poppy Control Act which, for the first time, required federal licensing of poppy cultivation. Commissioner Anslinger construed the law to mean that no such permits should be granted unless foreign supplies proved to be inadequate. This principle was set forth in Regulation Number Seven which implemented the Act. The Regulation remained in force until passage of the Controlled Substances Act in 1970.

Just as control interests became the basis for determining national policy on poppy cultivation, they were also used as the basis to determine foreign policy on the same issue. This policy was to limit cultivation of the poppy and production of opium to the smallest number of nations possible, especially recognizing those traditional sources which would otherwise be difficult to eradicate because of cultural factors. This principle was embodied in the 1954 protocol which, though strongly supported by the United States, never became a popular treaty.

In 1962, the Single Convention on Narcotics became the principal treaty for narcotic control even though it was opposed by the United States because it permitted all countries to cultivate poppy for their own needs and to export up to five tons annually for the world market. The United States viewed this as entirely contrary to its principles; however, in practice, such cultivations has spread much slower than might have been anticipated. Again, this is probably due to a combination of economic and legal factors.

There is no doubt that changing technologies have eliminated the economic factors that previously reinforced the U.S. policy of limiting poppy cultivation. Cultivation of either Papaver s. or Papaver bracteatum can be reliably and economically undertaken in many countries including the United States since modern methods of harvesting and production have eliminated the need for a large supply of cheap labor. This has been amply demonstrated in Australia, France, Turkey and elsewhere.

In 1975, U.S. processors of narcotic raw materials actually sought permission to cultivate Papaver bracteatum for the extraction of thebaine. After extensive public hearings in May of 1977, permission was denied on the grounds that it would have been contrary to U.S. international narcotics control policy.

Thus, narcotic control objectives have consistently determined U.S. foreign and domestic policy on cultivation and production of narcotic raw materials even in the face of changed economic considerations. Moreover, this policy has consistently favored the support of traditional foreign sources of poppy cultivation on the assumption that such support would:

- 1) discourage other nations not now cultivating narcotic raw materials from doing so, or from expanding existing production and thus adding to the possibilities for diversion to the illicit market;
- 2) help insure that production in the "traditional producer" countries, i.e., Turkey and India, went to satisfy the legitimate market and not the illicit market;
- 3) provide the United States with specifically related economic leverage to help encourage and assist those countries in controlling production and combatting diversion;
- 4) provide the United States with an adequate and reliable supply of narcotic raw material.

-18-

In 1972, events occurred which radically affected the availability of legitimate supplies. These were largely the result of aggressive U.S. narcotics control diplomacy directed at the specific problem of opium diversion in Turkey.

One of the ultimate results was the adoption by DEA of the so-called "80-20 Rule" in 1981. This Rule is a DEA-promulgated regulation (1312.13 CFR) which controls the issuance of import permits for narcotic raw materials. It represented the first articulated modification of the policy of previous decades but was, however, only a modification based on what had happened regarding the fourth assumption, and not otherwise a repetition or reversal of previous policy.

II. The Opium Shortage and the "80-20 Rule"

By the later 1960s, it was evident that the United States was undergoing a revolution in drug abuse far exceeding any previous national experience. We now see clearly that the problem was growing far more rapidly than were the government's resources, ability, or inclination to deal with it. It was spreading with the force of popular fashion aided and abetted (sometimes, but not always, inadvertently) by a greatly empowered and extended mass media.

Contrary to the public claims by drug advocates, it soon became clear that the abuse of heroin was also rapidly increasing as a part of this revolution. At that time, the great majority of the heroin entering the United States was produced from the illicit processing of opium harvested in Turkey from legitimately cultivated Papaver s. Traffickers would travel through the Turkish provinces in which opium was produced, buying part of the yield at inflated prices from the poor, generally illiterate Turkish farmers.

At this same time, the U.S. Bureau of Narcotics was expanding its overseas enforcement activities with the increasing interest and support of the Department of State. The result was to bring increasing diplomatic pressure on the Turkish government to ban poppy cultivation altogether as it appeared impossible for the government to control diversion.

The United States offered the incentive of a \$35 million dollar assistance package to aid the farmers in establishing an alternative crop. Although this plan was originally accepted by the Turkish government, it soon proved politically difficult and was abandoned in favor of an alternative approach. When it became clear that the government could not sustain the ban on cultivation, the U.S. specialists, with the support of the U.S., suggested that the Turkish government build a "poppy straw processing plant" which would result in eliminating the harvest of opium gum.

-19-

The Turkish government eventually decided upon this course of action, contracted for the construction of a modern poppy straw reprocessing plant, banned the harvesting of opium gum, and began a program of purchasing poppy straw (the dried poppy heads) from licensed poppy cultivators. This material was stored until such time as the processing facility became operational.

An immediate result was that Turkish opium gum, which had previously constituted about one third of the total U.S. purchases, was no longer available. This led U.S. manufacturers to complain of a major shortage and to search for alternative sources of supply. Thus, the traditional U.S. policy of favoring traditional sources had to be temporarily compromised to incur a continuing supply.

It was at this time that purchases were made from Australia, France, and Poland. At length, the shortage abated. By 1981, the period during which the "80-20 Rule" was being formulated, Turkey was preparing to operate its large poppy straw extraction facility and wished to re-enter the U.S. market. Turkey essentially opposed continuing U.S. trade with non-traditional countries, such as Australia, which it claimed had merely taken advantage of Turkey's self-imposed absence from the market while it successfully combatted its illicit traffic in opium.

The formulation of the "80-20 Rule" occurred within the traditional policy context of consideration of U.S. international narcotics control policy and the necessity to maintain an uninterrupted, reasonably priced supply for national medical needs.

Within this context, an effort was made to consider a number of equitable claims and to balance competing interests. Contrary to U.S. desires, a certain proliferation of poppy cultivation had occurred, in part, to respond to U.S. demand during the shortage. It seemed unlikely that these sources would now be eliminated whatever U.S. policy was adopted. Moreover, each of these countries in turn, through their representatives in Washington, laid claim to equitable consideration since they had supplied U.S. needs in a time of shortage.

Finally, in spite of Turkish representations, it was not known when they would actually be prepared to re-enter the market or how much material they would be able to supply. To re-close the market entirely to the traditional suppliers at that time would have meant giving the Indian government a de facto monopoly with which they would have been in position to dictate price and conditions to U.S. purchasers. In addition, questions of reliability of supply and protection against the

caprice of drought and international politics had to be taken into consideration.

The "80-20 Rule," when finally formulated, reflected all of these considerations. It reserved the bulk of the U.S. market for the two traditional suppliers which previous policy had supported. At the same time, those nations which had supplied the United States in time of need were permitted to collectively supply up to, but not more than, 20% of the need. This recognized their equitable claim and maintained a hedge against the vagaries of price, supply, weather, and politics. As developed, the 20% share could be expanded easily by regulation should the need arise. Australia, it was realized, would be the principal beneficiary of this relaxation.

The final rule also made it clear that the maintenance of status as a preferred supplier was in part dependent upon the maintenance of adequate controls against diversion into the illicit traffic.

III. Experience Under the Rule

The "80-20 Rule" must be evaluated on the basis of the limitations of any and all such policies. It did not, and could not, seek to guarantee that:

- 1) all production within these countries would be purchased;
- 2) all national stockpiles of opium or narcotic materials would disappear; and
- 3) all diversion would be eliminated.

Nevertheless, the policy has been successful within the context of a more realistic set of expectations and may be summarized as follows:

1) Turkey: Turkey originally lost its share of the international market as a result of responding to the pressure of the United States for elimination of the diversion of opium for the manufacture of heroin. It has benefited from the "80-20 Rule" with a partial restoration of its market share. Although the Turkish position is still economically difficult, there is no complaint regarding U.S. policy. The difficulties which Turkey is experiencing cannot be resolved by any trade policy which the United States might adopt.

2) India: The fortunes of India have fluctuated considerably under the "80-20 Rule." These are directly

related to the competition with Turkey. Recently, sales to U.S. firms have fallen because of increased purchases from Turkey. Although Indian authorities are unhappy with this decline, they do not blame U.S. policy which they strongly support. Alternatively, they realize quite well the linkage between their preferential treatment and drug enforcement. This was stressed in the course of the visit in March 1983, of Mr. Thomas, then-Assistant Secretary of State for Narcotics Matters, and Mr. Haislip, Deputy Assistant Administrator of DEA. The recent field study in India disclosed the considerable progress which has been made in drug law enforcement, both in terms of legislation and investigations. Clearly, the "80-20 Rule" has supported U.S.-India cooperation in this area; further improvements, however, are needed.

3) Australia: Australia is a highly efficient producer of narcotic materials which has principally benefited from the 20% allowed to non-traditional countries. There are no issues concerning diversion and control related to this production. The Australian government has expressed dissatisfaction with the 80-20 Rule because it wishes to compete for a larger share of the U.S. market. It regards the current limitation as contrary to general trade policies. However, from the perspective of the United States government, it does not appear that any further control or supply interest would be served by relaxing the Rule.

4) France, Poland, Hungary: Of the other nations permitted to compete for the 20 percent share of the market which has been set aside as a window of opportunity for countries other than Turkey and India, only France has on occasion exported quantities of CPS ranging from 15% of the national need in calendar year 1979 to 5% in calendar year 1987. This is a result of modern production similar to that which occurs in Australia: cultivation is managed by private individuals, but technological processing is done by a government-owned pharmaceutical plant. From the standpoint of U.S. policy considerations, the situation is otherwise identical to the case of Australia.

5) The United States: The United States government has had no problems in administering the "80-20 Rule." U.S. narcotics manufacturers have enjoyed a reliable and competitive supply of narcotic materials at low prices. No further world-wide proliferation of narcotic crop cultivation or production has resulted out of anticipation of possible access to U.S. markets. The Rule has answered all of the objectives of the United States government which could have been served by a decision of its kind.

IV. Possible Modifications

A stated purpose of the current study imposed by the Congress requires the consideration of modifications to the "80-20 Rule." The following options are worthy of comment:

1) Contraction of the Rule

This option would reduce or eliminate the 20% window of opportunity permitted to non-traditional suppliers such as Australia and France. Such a contraction would benefit either or both Turkey and India. It would help absorb some of the excess production capacity and stocks which are a problem for both countries and it would certainly receive their support. On the other hand, all the reasons which led to the creation of the "opportunity window" are still valid.

2) Expansion of the Rule

This option would expand or completely open the 20% window of opportunity to those recognized suppliers of the United States. However, there is no supply problem which the United States has experienced which would require such a move. In addition, it would further exacerbate the current surplus within India and possibly lead to increased diversion from India's fields at a time when we are actively trying to reduce the illicit markets. It would also be perceived in Turkey as a failure of U.S. support for the considerable sacrifices they previously made to curtail diversion of their opium production. Finally, there is no political or economic justification -- comparable to that which can be made for India and Turkey -- for extending such commercial opportunities to the industrialized nations since it would encourage production within these countries and thus tend to exacerbate the current problem of over-supply while increasing the dangers of diversion elsewhere.

3) Elimination of the Rule

This option would eliminate all restrictions relating to the country of origin for U.S. purchases of licit opium materials. This is a logical extension of the arguments in favor of eliminating the current official preference for Turkey and India. This, however, would lead to further proliferation of sources of narcotic material with attendant possibilities for increased diversion.

4) Maintenance of the Present Rule

The final option would maintain the Rule in its current form with adjustments as may be required or indicated by future developments. The facts and assumptions upon which the Rule was originally based have not substantially altered: current and future U.S. needs can be adequately met under this process. Thus, although some adjustments are called for on the part of the traditional suppliers, the Rule is serving the purpose to which it is suited within its limits to influence conditions.

V. Recommendations

The review has shown that the "80-20 Rule" has met its stated objectives and, with adjustments, can be expected to continue to do so while current conditions remain in effect.

It is recommended that the Rule remain in effect for an additional three years, during which the United States government should actively work with the traditional producing nations to correct current and potential imbalances in production or stockpiling. Retention of the Rule as currently constituted beyond that point should be dependent upon the response of the traditional suppliers to the needed revisions or changes to their programs, policies, and/or procedures.

During this period, the United States should continue to support India as a traditional supplier of the licit raw material, subject to the conditions of the Rule, while entering into negotiations with India to correct imbalances caused in part by the operation of the Rule. These negotiations should encourage India to take action to reduce the opportunity for diversion from the field by expansion of enforcement and inspection control. India should also be encouraged to consider a partial conversion to the concentrate of poppy straw process to further reduce the potential for diversion from the field. The negotiations should also seek to assist India in reducing its opium stockpile, to bring its production into line with current market conditions and to develop realistic long-range production estimates.

The United States should also continue to support Turkey as a traditional supplier of the licit raw material subject to the conditions of the "80-20 Rule." However, the United States should actively encourage Turkey to consider production of alternative products which require extraction from plant raw material (ranging from bella donna to licorice) as a means of utilizing the full capacity of its processing factory in lieu of expanding the areas of poppy cultivation.

It is also recommended that the United States should provide direct and indirect assistance, to the extent available, to aid India and Turkey in meeting the stated objectives. In addition, it is recommended that the United States should provide, to the extent possible, increased training of anti-narcotics officials in India to reduce the possibility of diversion from the field, and with border and customs officials in India and Turkey to decrease the potential of illicit transit through those countries of illicit narcotics and to better regulate the flow of precursor chemicals.

At the end of the three-year period, the "80-20 Rule" should be reexamined. Continuing or restructuring the Rule should be reevaluated in part on the basis of the responses and actions of Turkey and India, the major licit opium producing nations, to the above.

Finally, in recognition of the favored position granted to the small group of licit opium suppliers, the United States should continue to be sensitive to any formal or informal agreements which seek to establish price levels above the customary competitive levels. Although there has been no indication that such price-setting agreements have ever existed, the possibility of such actions does exist. In the event of such an occurrence, an immediate revision of the existing Rule would be undertaken by the government without delay.

COUNTRY REPORTS:

TURKEY

I. Turkey's Role as a Supplier of Raw Material

Opium poppies are legally grown in Turkey under government control and supervision for the production of poppy straw and the further conversion to concentrate of poppy straw (CPS).

In recognition of the historically significant role of opium poppies in Turkish culture, especially peasant culture, Turkey has been recognized by the international community as a "traditional" supplier of narcotic raw materials (NRM). It has also been accorded that status under United States law by the Drug Enforcement Administration's "80-20 Rule" which guarantees 80% of the U.S. market in NRM to traditional suppliers (Turkey and India).

The poppies are grown by licensed farmers throughout eight provinces plus four counties of a ninth. The provinces involved are Afyon, Isparta, Denizli, Uşak, Burdur, Kütahya, Amasya, Çorum, and four counties of Konya province. Poppy cultivation was permitted in Amasya and Çorum provinces for the first time in 1988. This was the first expansion of opium poppy cultivation outside the seven original provinces although there have been annual increases in the total acreage licensed for cultivation.

The following chart provides the latest available estimates for poppy cultivation in Turkey from 1981/1982 through 1987/1988. The figures, submitted by the DEA Ankara Country Office (C.O.), are keyed as follows:

- (A) Year (licensed harvested)
- (B) Number of licenses issued to farmers
- (C) Licensed area (hectares)
- (D) Harvested area (hectares)
- (E) Poppy straw produced (metric-tons)
- (F) Poppy straw yield (kilograms per hectare)

(A)	(B)	(C)	(D)	(E)	(F)
1981/82	66,600	18,000	8,500	5,800	685
1982/83	63,300	16,900	7,000	3,700	530
1983/84	69,000	17,300	12,600	8,000	635
1984/85	75,300	17,600	5,000	2,500	500
1985/86	38,000	19,000	5,400	3,500	648
1986/87	63,000	20,800	6,000	3,600	600
1987/88	103,900	35,000	18,200	9,870	541

-26-

* It should be noted that there are variances in the figure provided in this report as compared to those reported to the International Narcotics Control Board.

The chart graphically illustrates the dramatic expansion in all categories with the exception of poppy straw yield which has not again approached the figure attained in 1981/82.

Opium poppy planting and harvesting is a peasant industry in Turkey both planting and harvesting are done entirely by hand. The poppies, which are grown for their seeds and for poppy straw, are planted in the fall of one year and harvested in July or August of the following year. The poppies are grown for poppy straw; no opium gum is produced.

The Turkish government licenses all farmers who wish to grow opium poppies. Paddocks are limited to a maximum of five declares (one-half hectare), although the average planted is currently about three declares.

The planning and licensing of poppy production is the responsibility of the Opiates Board of the Turkish Soil Productions Office (TMO). Cultivation is controlled by TMO and Jandarma (paramilitary police) personnel who patrol and inspect the paddocks. Since no opium gum is legally produced in Turkey, farmers are forbidden to incise the poppy capsules. As a result of the controls instituted by the Turkish government, there is no illicit collection or production of raw opium in Turkey.

After they have dried on the stem, the poppy capsules are picked by hand. The seeds are removed from the capsules and are sold for about 350 Turkish Lira per kilogram. They are used extensively for cooking oil and animal feed. The remaining poppy straw must be sold to the Opiates Board.

The poppy straw is used to produce concentrate of poppy straw (CPS) at the government owned Bolvadin alkaloids factory in Afyon Province. The plant has a production capacity of about 20,000 tons of poppy straw per year. Yields have averaged from 0.45 to 0.50%.

No diversion of poppy straw or CPS has been noted since poppy cultivation was resumed in 1974-75.

Information provided by DEA Ankara indicates that as of December, 1988, Turkey had stockpiles of approximately 35 tons of CPS, 10,000 tons of poppy straw, and 25 tons of (pre-1972) opium gum. The morphine content of the CPS is approximately 80%.

In 1988 Turkey produced 42 metric tons of alkaloids at the Bolvadin factory.

-27-

Reported exports from Turkey in 1988 were as follows:

Anhydrous morphine alkalioid (AMA)	44.5 metric tons
Codeine and Codeine phosphate	47.45 " "
Dionine	200.0 kg.
Raw opium gum	27.0 kg.
CPS	44.5 metric tons

Turkey's major trading partners for narcotic raw materials (NRM) are:

Bulgaria.....	opium gum
Switzerland.....	opium gum, codeine
Netherlands.....	poppy straw, CPS, codeine
Belgium.....	poppy straw
U.S.....	CPS
U.K.....	CPS
Canada.....	codeine
FRG.....	codeine
Denmark.....	codeine, CPS
Egypt.....	codeine
GDR.....	codeine
Iraq.....	codeine
Thailand.....	codeine

There are several special factors concerning the opium poppy industry in Turkey which, for purposes of this study, must be considered.

First, as indicated, poppy growing is a traditional peasant industry in Turkey. The government has allowed the number of licensees to increase dramatically. Because of the constituency politics vis-a-vis the licensees, the social disruption which would be caused if the government again banned production, the traditional uses of poppy by-products and the substantial investment in the poppy straw processing plant at Bolvadin, it is axiomatic that Turkey will continue to cultivate opium poppies.

A second special factor which should be considered in this examination of U.S. narcotic raw material acquisition policy is Turkey's past cooperative efforts, made at considerable domestic political costs, in eliminating itself as a source country for heroin. As is well known, Turkey first banned opium production entirely. When production was resumed in 1974/75, Turkey converted to the CPS process at substantial cost at the request of the United States. Opium gum production was prohibited. As a result, Turkey feels that it is "owed" some special consideration by the United States.

The Third special factor is Turkey's historical reliability, both as a supplier of NRM and as a NATO ally. Here again the Turkish government would, in all probability, feel that it was deserving of special consideration.

II. Turkey's Role in the Drug Traffic

Prior to Turkey's ban on the production of opium, a large percentage of the heroin reaching the United States was derived from Turkish opium poppies. The story of the French Connection is well known. This situation changed dramatically with the introduction of the CFS process coupled with strict governmental controls. For all practical purposes, the Turkish Government has effectively eliminated any diversion of opiates from legally produced stocks. Turkey, therefore, is no longer a source country for heroin.

However, heroin and morphine base, enters Turkey from Pakistan, Afghanistan, and Iran. The majority is smuggled across the Iranian border although lesser amounts enter Turkey from Syria. According to the DEA Ankara C.O., laboratory activity increased considerably in Turkey during the past year. Generally, fully processed heroin enters Turkey from Afghanistan and Pakistan while morphine base is manufactured in Iran and smuggled into Turkey for conversion into heroin. It appears that wholesalers prefer Turkish processed heroin because it is generally more potent and thus commands higher prices. Also, precursors, laboratory supplies and qualified chemists are more readily available in Turkey. Additionally, the laboratories are increasingly under the protection of terrorist groups who are financing their activities through heroin trafficking. The Kurdish populace living on both sides of the Turkish/Iranian border is heavily involved in smuggling narcotics into Turkey. Kurds also control much of the heroin supply system in Turkey.

Heroin and morphine base are often moved overland through Eastern Europe in "trapped" cars driven by Turkish guest workers who have a legitimate reason to travel between Turkey and Western Europe. TIR trucks, which transit international frontiers without Customs inspection, are also often used to smuggle narcotics to Europe. In addition, Turkey's geographic position as a land bridge between the Middle East and Europe make it a significant transit country.

III. Nature and Effectiveness of Law Enforcement Efforts - Cooperation with the United States

The DEA Ankara C.O. has reported that the Turkish Government views narcotic trafficking as a serious internal problem which is often directly related to terrorist activity. An increase in domestic drug abuse has also contributed to government sensitivity to the problem. Emphasis continues to be placed on narcotic law enforcement.

A number of government agencies have responsibility with regard to the enforcement of narcotic laws. Among them are the Turkish National Police (TNP), the Jandarma, Customs, the Coast Guard, and

-29-

the Opiates Board of the Turkish Soil Products Office. The Ministry of Foreign Affairs also plays a significant role through its responsibility for multilateral narcotic enforcement efforts and for cooperation between Turkey and other countries in narcotics enforcement.

Seizures made by Turkish authorities during the past three years, as reported by DEA, are as follows:

<u>Year</u>	<u>Heroin (kg.)</u>	<u>Morphine Base (kg.)</u>
1986	155	54
1987	1343	323
1988	1250	394

AUSTRALIA

I. Australia as a Supplier of Raw Material

Opium poppies are legally grown in Australia only on the island state of Tasmania. No cultivation is allowed on the mainland. The poppies are grown for harvesting as poppy straw. No opium gum is produced. According to INCB estimates and information provided by the Tasmanian Poppy Advisory and Control Board, there are currently about 5,000 hectares of poppies being cultivated. INCB statistics for the years 1983-1987 show Australian cultivation as follows:

<u>Year</u>	<u>Area (ha)</u>	<u>Poppy Straw Harvested (kg)</u>
1983	5273	3,977,000
1984	5738	4,828,000
1985	4851	4,153,000
1986	3994	4,101,000
1987	3274	3,000,000

Tasmania is limited in its ability to support a large expansion of the poppy growing area (currently concentrated in the north and in the Derwent Valley in the south) due to limited availability of the proper soil needed for poppy germination. As a practical matter, Australian officials claim that, considering soil conditions in Tasmania, the cultivated area can only be increased 10-15% with further increases generated by increased yields. It should be noted that opium poppies grown by the two private firms involved in the cultivation in Tasmania provide the highest yields in the world.

The following chart provides INCB statistics for the extraction of alkaloids from poppy straw from 1983-1987:

-30-

<u>Year</u>	<u>Poppy Straw Used (kg)</u>	<u>CPS Manufactured (kg)</u>	<u>Yield (%)</u>
1983	4,421,477	87,533	1.98
1984	4,105,778	85,314	2.08
1985	4,184,157	94,227	2.25
1986	5,002,556	92,680	1.85
1987	3,922,766	83,011	2.12

The Poppy Advisory and Control Board, an agency of the State of Tasmania charged with oversight of the poppy growing industry, does not permit the stockpiling of large quantities of raw product. About 2-3 months worth of buffer stocks are maintained.

For the 1988-89 growing season 450 farmers received licenses from the Poppy Board to grow poppies based upon their contracts with one or both of the firms. The farmers involved are mainly vegetable growers who use poppies as a rotational crop. The farmers are paid on the basis of the alkaloid content of their crop.

Australian poppy straw is converted to concentrate of poppy straw (CPS). The CPS was exported as follows in 1987 (INCB statistics):

United States	18,221 kg.
United Kingdom	30,325 kg.
Norway	4,740 kg.
Denmark	2,953 kg.
Yugoslavia	2,185 kg.
Italy	2,988 kg.
Belgium	1,199 kg.

Australian trade relations with regard to narcotic raw materials (NRM) are complicated vis-a-vis the United States because of the "80-20 Rule." During 1988-89 the Australian opium poppy industry and various governmental entities at both the state and federal level have made representations for the abolition or modification of the rule. The Australian position is that the "80-20 Rule" distorts the free market and normal trading patterns. They also claim that it has been ineffectual in its attempt to limit and stabilize the raw material stocks.

Some elements of the Australian government, particularly the Department of Foreign Affairs and Trade, tend to view the issue as a bilateral trade disagreement. This feeling is perhaps intensified by other bilateral trade problems (e.g., wheat) which have occurred between the United States and Australia. In addition, the Australian poppy industry sees itself as highly efficient, competitive, and secure.

Although Australia claims not to be able to supply all the licit U.S. needs, the industry is most eager for the opportunity to compete for a larger share of the market.

For purposes of this study there are several special factors which must be considered with regard to Australia. First, the Australian poppy growing and processing industry is technologically sophisticated and, in all practical terms, totally secure.

Australian poppies currently yield morphine, codeine, and thebaine. Through an extensive breeding program, the Australian industry claims that it will be able to provide poppies that produce all of the naturally occurring alkaloids. There is no question of diversion or stockpiling of product. Australian government and industry representatives believe that to favor inefficient peasant production in other countries under these circumstances is a total distortion of economic reality.

Secondly, Australia believes that it provides a Southern Hemisphere poppy capability which is protected from drought by irrigation. This, in the Australian view, helps to insure against any future supply disruptions among traditional suppliers such as have occurred in the past. Australians believe, therefore, that it is in the United States' own interest to help assure the viability of this industry by providing a more "level playing field."

Third, Australian industry officials have emphasized that they have no interest in attempting to displace India and Turkey as a supplier of the licit U.S. needs. As indicated above, Australia is apparently incapable of doing so because its ability to expand production is limited. Australian officials do admit that they do want the opportunity to compete for more than the 20% of the U.S. market to which they are now limited.

Lastly, Australians point out that Australia is a reliable source of supply and an ally of the United States and thus should be deserving of some special consideration.

II. Australia's Role in Drug Traffic

As stated above, the Australian opium poppy growing and processing industry is extremely secure. There is no indication that any Australian product has ever been diverted to illicit heroin production. What little diversion there has been, has been unorganized and petty in nature. No growers have ever been involved. In 1988 approximately 26,000 capsules were lost. This represents about 1% of 1 hectare. 95% of this amount was accounted for and the street rate was 100%.

Australia is a producer of illicit marijuana. Estimated 1988 production is about 1 million pounds (approximately 454 metric tons). Marijuana cultivation tends to be controlled by foreign organizations. In recent years there has been a trend for growers to cultivate smaller, well camouflaged fields in areas of restricted accessibility.

The popularity and availability of amphetamines in Australia has been increasing. A number of clandestine laboratories have been seized. It appears that these labs supply the domestic market only. There is no evidence of export. Precursor chemicals are obtained from local sources. Amphetamine production and distribution is heavily influenced by the numerous outlaw motorcycle gangs operating in Australia.

Heroin trafficking in Australia is fragmented with involvement by many smaller groups and individuals. Cocaine trafficking continues to be insignificant, but it is expected to worsen.

At the present time, there seems to be very little evidence of diversion of pharmaceutical products or chemicals. Australian enforcement officials have expressed interest in attempting to set up a monitoring system with particular emphasis on the targeting of amphetamine precursor chemicals.

To date there is no evidence indicating any organized drug transshipment occurring in Australia. The vast majority of illicit drugs entering Australia are destined for local markets with a small spillover to the New Zealand market.

III. Nature and Effectiveness of Law Enforcement Efforts and Cooperation with the United States

The Government of Australia places a high priority on efforts to curtail illicit drug trafficking. In 1984, the Prime Minister launched a national campaign against drug abuse. In 1985, federal, state, and territorial heads of government met in a "Drug Summit" and pledged their governments to do everything possible to combat growing drug abuse in Australia. In 1987-1988 the Commonwealth Parliament passed new legislation addressing asset forfeiture, banking transaction/records, telephone intercept and mutual assistance matters.

Narcotics law enforcement in Australia is shared by federal, state and territorial police agencies. Each police force is an independent organization with jurisdiction over laws of the Commonwealth or of the particular state or territory. At the federal level, the agencies involved in narcotics law enforcement are the Australian Federal Police, Australian Customs Service, National Crime Authority, and the Australian Bureau of Criminal Intelligence.

INDIA

I. India's Role as a Supplier of Raw Material

Opium poppies are legally grown in India under governmental control and supervision for the production of opium gum. Poppy growing has played a significant historical role in peasant culture in several areas of India. In recognition of this fact, India has been accepted by the international community as a "traditional" supplier of narcotic raw materials. It has also been accorded that status under United States law by the "80-20 Rule" which, in effect, reserves 80% of the U.S. market for the traditional suppliers (India and Turkey).

Licit opium poppies in India are grown under the auspices of the Narcotics Commissioner, located in Gwalior, Madhya Pradesh state. Poppies for licit production are grown pursuant to a governmental licensing system in three states only: Madhya Pradesh, Rajasthan, and Uttar Pradesh. Planting is undertaken during October-November for harvesting the following February-March. Each year the Narcotics Commissioner determines the acreage which will be licensed for planting, taking into consideration criteria including existing stocks and projections of future demand. The entire process of opium production, including the licensing of the farmers, collection of the raw opium, and export or conversion to alkaloids for domestic use, is overseen by the staff of the Commissioner.

The following chart, while demonstrating the government of India's efforts to reduce opium production due to the drop in world demand, also shows the troubling concomitant rise in opium stocks (Data based on information provided by the DEA New Delhi Country Office).

<u>Crop Year</u>	<u>Area Under Poppy Cultivation</u>	<u>Number of Cultivators</u>	<u>Opium Stocks (Metric Tons)</u>
1977-78	62,684 ha	245,161	816
1978-79	52,082 ha	216,205	1311
1979-80	35,167 ha	172,188	1607
1980-81	36,672 ha	172,188	2500
1981-82	36,672 ha	172,188	3000
1982-83	32,000 ha	172,188	3000
1983-84	25,520 ha	131,000**	3000
1984-85	25,500 ha	130,000	3000
1985-86	23,000 ha	130,000*	3000
1986-87	23,000 ha	129,000*	3000
1987-88	23,338 ha	160,909	1642
1988-89	15,000 ha	160,909	2000

* Estimates

** Low total due to crop failure

The Government of India operates two manufacturing facilities for processing opium: one at Chazipur in Uttar Pradesh, and the other at Nimach in Madhya Pradesh. Neither of these plants can be considered efficient.

Farmers are paid by the government on the basis of a formula on yield per hectare: the higher the yield, the greater the price per kilo. The farmer takes his harvest to a district collection point where the opium is weighed and payment procedures take place.

It is difficult to speculate on whether or not the Indian government would consider a further significant reduction of the area under cultivation or a reversing of the increases which have occurred since the mid-1980's in the number of licensed farmers. It is clear, however, that further reductions cannot be made under present conditions without incurring economic hardship in the growing areas which would entail a high political cost to the government.

In 1987 India exported opium gum as follows:

United States.....	181,001 kg
USSR.....	150,001 kg
United Kingdom.....	94,006 kg
Japan.....	60,000 kg
France.....	18,200 kg
FRG.....	2,000 kg

India's trade relations with regard to narcotic raw material are, of course, greatly influenced by its quasi-legal status as a traditional supplier. As has been indicated, this status was granted to India and Turkey through a resolution of the U.N. Commission on Narcotic Drugs (CND) in recognition of the historical and cultural significance of poppy cultivation in the two countries.

The CND resolution was aimed at maintaining a world-wide balance between the supply of the licit raw material and the legitimate demand. It encouraged importing countries "to support the traditional supply countries..."

Although the resolution was given the weight of law in the United States by the "80-20 Rule," it is probably fair to say that it was honored more in the breach in other countries. However, regardless of the reason, as the previous charts show, India has been unable to find a balance between what it produces and what it can sell. The end result is a substantial stockpile of opium gum in India.

-35-

There are a number of special factors which must be given consideration in the context of this study.

First, and probably most important, is the issue of control. The U.S. acquisition policy historically has been based upon the principle of keeping the number of opium-producing countries to a minimum. The United States government has, in this regard, set an example by not permitting the cultivation of opium poppies within its own territory. The issue of control, or the prevention of diversion, was given clear precedence over commercial considerations; in the historical context of this policy, free trade was unthinkable. Thus, a reaffirmation of the traditional policy, implied in this report, is inconsistent with India's large stockpile, now totalling approximately 2,000 metric tons of opium gum, which represents a need for proper planning and control.

The issue of control leads logically to a second special factor: a constituency-based political problem of major proportions with which the Indian government is faced. Poppy cultivation in India is a centuries-old labor-intensive peasant industry. It has traditionally provided a subsistence-level livelihood for a substantial number of families. India has, as indicated, attempted to bring the total area of permitted cultivation into line with market conditions by decreasing the size of the average plot permitted to the licensees.

Unfortunately, this policy has not made the opium stockpile disappear. It appears that further reductions in the total hectares for which cultivation is permitted, or in the number of licensed farmers, may be destabilizing and in fact may even be counter-productive to attempts to prevent diversion. It will have to be determined whether the growers will cooperate with the Indian government if India attempts further reductions, or if they will attempt to continue their traditional production of poppies which would enter the growing world-wide illicit market.

In large part, the resolution of this issue may be dependent upon the alternative opportunities for income made available to the traditional opium farmers. An issue for bilateral discussions between India and the United States during the upcoming three year period, and upon which the retention or modification of the Rule at the conclusion of that time period may in part be based, will obviously include this issue and the actions taken in attempting to resolve this potential problem.

Another special consideration for purposes of this study is the fact that India is the only large scale commercial producer of opium gum in the world. As is more fully discussed elsewhere in this study, opium gum has some unique properties which, as

2.

THE AUSTRALIAN GOVERNMENT BELIEVES THAT, REGARDLESS OF ITS ORIGINAL OBJECTIVES, THE 80:20 RULE HAS NOW BECOME AN UNFAIR TRADING PRACTICE MASQUERADING AS A NARCOTICS CONTROL MEASURE. DIVERSION WOULD BE LESS LIKELY IF CERTAIN COUNTRIES WERE NOT ENCOURAGED TO OVERPRODUCE. MARKET ACCESS FOR NARCOTIC RAW MATERIALS, INCLUDING TO THE U.S. MARKET, SHOULD BE REGULATED ONLY BY THE PROVISIONS OF THE SINGLE CONVENTION AND ITS AMENDING PROTOCOL OF 1972 AND BY ARTICLES XI AND XIII OF THE GATT. MARKET DISCIPLINE, NOT MARKET PROTECTION, IS REQUIRED TO REDUCE PRODUCTION, GRADUALLY REDUCE STOCKPILES, AND REDUCE THE RISK OF DIVERSION; IN SHORT TO ACHIEVE THE OBJECTIVES FOR WHICH THE 80:20 RULE WAS DESIGNED.

AUSTRALIA'S COMMERCIAL INTERESTS HAVE BEEN ADVERSELY AND UNJUSTLY AFFECTED BY THE 80:20 RULE. IF IT WERE ABOLISHED AUSTRALIA WOULD HOPE TO INCREASE ITS PRODUCTION OF NARCOTIC RAW MATERIAL BY ABOUT 20 PERCENT ON A SUSTAINED YIELD BASIS OVER A PERIOD OF ROUGHLY FIVE YEARS. WHILE THIS WOULD SUBSTANTIALLY IMPROVE THE TASMANIAN INDUSTRY'S COMMERCIAL PROSPECTS, IT WOULD NOT/NOT ENABLE AUSTRALIA TO DOMINATE THE U.S. MARKET.

AUSTRALIA HAS THE MOST SECURE AND EFFICIENT INDUSTRY IN THE WORLD. FOR SECURITY REASONS OPIUM POPPIES ARE ONLY GROWN IN THE ISLAND STATE OF TASMANIA BY A SMALL NUMBER OF LICENCED FARMERS. VERY TIGHT CONTROLS ARE IMPOSED AT ALL STAGES IN THE PRODUCTION PROCESS. IN ADDITION, THE HIGH MORPHINE YIELD PER HECTARE HAS KEPT THE AREA UNDER CULTIVATION RELATIVELY SMALL IN COMPARISON WITH THAT OF OTHER MAJOR PRODUCERS. (SEE PAGE 5 OF ACCOMPANYING AIDE MEMOIRE.) AUSTRALIA WORKS ACTIVELY IN MULTILATERAL FORA AND IN REGIONAL COOPERATION PROGRAMS (INCLUDING IN PROGRAMS WITH THE UNITED STATES) TO PREVENT THE PRODUCTION AND DISTRIBUTION OF ILLICIT NARCOTICS. AUSTRALIA ASKS THE COMMITTEE TO CONSIDER WHY A SECURE, EFFICIENT, COMPETITIVE INDUSTRY WHICH OPERATES IN CONFORMITY WITH ITS INTERNATIONAL OBLIGATIONS SHOULD BE PENALISED IN FAVOUR OF INEFFICIENT AND INSECURE COMPETITOR(S) WHICH DO NOT PROPERLY FULFIL INTERNATIONAL OBLIGATIONS?

AUSTRALIA URGES THE COMMITTEE SERIOUSLY TO QUESTION THE RECOMMENDATIONS OF THE ADMINISTRATION'S REPORT ON "LICIT OPIUM PRODUCTION" SUBMITTED IN ACCORDANCE WITH SECTION 4307 OF THE ANTI-DRUG ABUSE ACT OF 1988. AUSTRALIA BELIEVES THAT THE 80:20 RULE SHOULD BE ABOLISHED. AS IMMEDIATE ABOLITION WOULD CAUSE THE KIND OF MARKET DISTORTION WE ARE ALL ANXIOUS TO AVOID, AUSTRALIA RECOMMENDS PHASED ABOLITION OVER THREE TO FIVE YEARS.

020437

///

Mr. Chairman, Members of the Committee:

My name is Julian Ormond GREEN. I am the Chairman of the Poppy Advisory and Control Board, State Government of Tasmania, Australia. I am also the Secretary of the Tasmanian Department of Justice.

The Poppy Advisory and Control Board (PACB) regulates the industry growing the Papaver somniferum poppy plant for the production and manufacture of codeine and narcotic raw material (morphine) in the form of concentrate of poppy straw (CPS) and extraction of other useful alkaloids from the poppy using the straw process.

The opium gum process is not used and has never been used in Tasmania in the production of narcotic raw material.

Because Australia has a small domestic market for narcotic raw material, over 90% of the Australian production is exported.

1. OVERVIEW OF THE INDUSTRY IN TASMANIA

1.1 The Australian poppy industry, based in Tasmania, is unique as a vertically integrated industry, embracing the application of highly sophisticated, chemical processing technology to a natural crop which is ideally suited to the island State of Tasmania because of the combination of agricultural and security factors.

1.2 Agricultural factors include rich soils, highly educated farmers, reliable spring and early summer rains and access to irrigation, followed by long hours of sunlight when the poppy crop is reaching biological maturity. From the point of view of security, Tasmania's island status and the existence of a law-abiding and (relatively) drug-free local population are of vital importance.

1.3 All poppy cultivation and initial processing, as well as a significant proportion of extraction and manufacture, is undertaken in Tasmania. Some extraction and manufacturing activity takes place in the State of Victoria, which is adjacent to Tasmania and part of the Australian mainland.

1.4 Strict domestic and international controls are required because of the narcotic content of the plant. Governments of producing countries are required by international agreement to carefully control and supervise all stages of growing and production under the terms of the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol). By agreement between the Commonwealth and all State Governments, and consistent with the requirement under the Single Convention to carefully control the growing and production of opiates, Australian cultivation of the poppy is restricted to the island state of Tasmania. The physical separation from the major centres of population and illicit drug abuse is advantageous in minimising the risk of opiate raw material finding its way into the illicit trade.

1.5 The Australian opiate industry is based on the processing of dry poppy plant material known as poppy straw. The crop is planted in Autumn and Spring in Southern Tasmania and in Spring in Northern Tasmania.

1.6 The plant is grown to biological maturity and mechanically harvested in December-March when the poppy capsules are dry. The seed is then separated from the capsule, cleaned and bagged ready for sale. The alkaloids are extracted only from the poppy straw. Poppy straw consists of the capsule and up to six inches of the upper stem of the plant, but does not include the seeds which are free of opiates.

1.7 While this method of extraction is similar to that now being used by Turkey and some European countries, it has been extensively refined in Australia to the extent that the morphine concentrations in Tasmanian poppies and poppy straw yields are the highest in the world.

1.8 A clear distinction exists between the poppy straw process and the traditional method of manually lancing the green capsule and collecting the opium latex by hand. This latter method is used by India, the world's largest producer and exporter of opiate raw material. The poppy straw process and method of harvest ensure that most poppy plant material is removed from the paddock and transported in sealed bins to secure storage at the two processing factories. The use of large mechanical harvesters makes for an extremely efficient and fast harvesting operation involving very few people, all of whom have been security cleared. The small amount of poppy stubble remaining in the fields after harvest is destroyed under Government supervision.

1.9 The manual method of lancing and collection of opium is more labour intensive and time consuming. As opium has a relatively high content of morphine compared to straw, and is itself a material subject to abuse, there is a proven substantial degree of diversion of opium to the illicit market by the large numbers of farmers and others involved in its collection.

1.10 The major opiates produced from the oil poppy grown in Tasmania are morphine, natural codeine and thebaine. The poppy straw process involves primarily the production of concentrate of poppy straw (CPS), which is essentially a crude extract of the alkaloids, mainly morphine and, secondly, the extraction of natural codeine and thebaine.

1.11 Opiates produced from poppies grown in Australia are exported mainly in the form of concentrate of poppy straw (CPS) and codeine; lesser amounts of other opiates, such as pholcodine and dihydrocodeine, and of thebaine and its derivatives are also exported. CPS and thebaine are used in the manufacture of a number of opiates used in pharmaceutical preparations, mainly codeine from CPS.

1.12 Development of the industry, the nature of Government involvement and security applying to the industry are set out in Appendix I. A table setting out the history of poppy growing in Tasmania is provided in Appendix 2.

2. TASMANIA'S INDUSTRY AND THE 80/20 RULE

2.1 From the inception of the 80/20 Rule, the Tasmanian Government and the two processing companies - Tasmanian Alkaloids (Johnson & Johnson) and Glaxo Australia (Glaxo Holdings, UK) - have awaited the opportunity to have the Rule subjected to an objective review procedure to enable the operation of the Rule, in the light of the situation presently applying in the international narcotics market, to be assessed. In addition, a review procedure is sought to enable the original objectives of the Rule to be evaluated in the changed circumstances now prevailing in the industry.

2.2 The requirements of processing companies for narcotic raw material are not static and the Rule, because of its inflexibility, has created unwanted distortions which need to be urgently addressed.

2.3 Tasmania's interest in the Rule, and its operation, stems from the time when Tasmania was a party to the hearings in 1980/81 before Administrative Law Judge, the Honourable Francis L. Young.* At that time, the DEA, in response to Resolution 471 of the Commission on Narcotic Drugs, sought to establish an embargo upon the importation into the United States of CPS from Australia. Resolution 471 warned that narcotic raw materials were being produced in excess of the world's legitimate needs and urged action to balance production with world-wide needs.

2.4 Production of narcotic raw material in the form of opium gum and poppy straw in excess of demand resulted in India and Turkey accumulating large inventories of stock over and above that required to meet, on a sustained basis, the world's needs. This accumulation occurred contrary to the provisions of the Single Convention on Narcotic Drugs of 1961, the provisions of which require production to be limited to meet forward orders and sufficient to accumulate a reserve trading stock. Resolution 471, and subsequent Resolutions passed by the Commission on Narcotic Drugs, may be characterised as an attempt to retrospectively validate excess production and accumulation of stocks by India and Turkey contrary to the provisions of the Single Convention. The Resolutions are most likely ultra vires the Commission and the 1961 Single Convention.

* See Report to the Administrator, IN THE MATTER OF Proposed Limitations on Imports of Narcotic Raw Materials, DEA Docket No. 80-18, January 16, 1981.

2.5 It is important to note that, since 1988 the Commission on Narcotic Drugs has abandoned the line of Resolutions similar to Resolution 471 on which the 80/20 Rule was based. The Commission realised that the giving of preferential marketing consideration to select producers has not resulted in a reduction of stock or contributed to improved security and less diversion to the illicit market.

2.6 As a result of the 1980 hearings before Judge Young, the so-called 80/20 Rule was promulgated by the DEA (21 CFR para. 1312.13(g)). That Rule requires a minimum of 80% of all narcotic raw materials imported into the United States to come from India and Turkey. The Rule was designed as a mechanism to reduce excessive stocks held by those two countries by providing them with a guaranteed outlet to the U.S. market. History has shown that the market share guaranteed India and Turkey was met, not from the excess stock accumulated by the two countries, but from continued and at times increased annual plantings of the opium poppy. In this respect, the Rule has failed to act as an instrument to bring down stocks.

2.7 Additionally, the Commission on Narcotic Drugs believed that through an orderly reduction of excess stocks, the risk of diversion to the illicit market from those stocks would be eliminated. In reality, there has not been a problem of diversion from the accumulated stocks. Nevertheless, in the case of India, diversion from licit production is an increasing problem and it would appear that this diversion is taking place at the level of the farmer. There is no need to emphasise the point that the production of narcotic raw material using the labour intensive opium gum method lends itself to major diversion of raw material into the illicit market.

020437 /17

7.

2.8 Under the 80/20 Rule, the maximum of 20% of the U.S. market is reserved for five other authorized producers, being France, Poland, Hungary, Yugoslavia and Australia. Australia (Tasmania) presently enjoys as much of the 20% maximum as can be achieved in any year. As a consequence of the Rule, a cap has been placed on the ability of the Tasmanian industry to produce additional CPS for the U.S. market. The direct and immediate effect is to limit the ability of Tasmanian Alkaloids and Glaxo Australia to supply more CPS to the U.S. market.

2.9 The 80/20 Rule was adopted without distinction being made between the unique qualities offered by CPS as a narcotic raw material over and above that of opium. Since 1980, the distinction between the two commodities as narcotic raw material has been accentuated. It is indisputable, as shown by INCB statistics, that the world-wide demand for opium gum as a narcotic raw material for the manufacture of narcotic drugs is declining. This decline world-wide is also reflected in the preferences now evidenced by U.S. manufacturers for CPS over opium gum. The 80/20 Rule, as formulated and in its operation, wrongly assumes that opium gum and CPS are interchangeable commodities. The decline in the use of opium as a narcotic raw material has been temporarily arrested following the failure of the 1989 Turkish crop.

2.10 Tasmania at present produces 50 tonnes per annum of codeine and narcotic raw material in the form of concentrate of poppy straw. The morphine quantity of the CPS is manufactured to meet the customers' requirements. Due to geographical limitations applying to Tasmania, the availability of soils and competition from other highly remunerative cash crops, it

is estimated that Tasmania could only increase production of CPS and codeine on a sustained basis by between 10 to 15 tonnes per annum.

2.11 As the industry is confined to the island State of Tasmania for security reasons, any extension of the industry to the mainland of Australia is not in contention. Tasmania therefore is not in a position under any lifting of the 80/20 Rule to dominate the United States market to the exclusion of Turkey or India. Tasmania supplies important and valuable markets in Europe and these would not be surrendered in order to further service the U.S. market.

2.12 Tasmania's interest in a review of the 80/20 Rule was stimulated following the publication of a proposed Amendment to the US Foreign Assistance Bill for 1987 to ban imports of Indian opium. Tasmania's position on that proposal was that any action in relation to changes in the U.S. import policy on narcotic raw material should involve a thorough review of the whole of the U.S. import policy - not just opium - and that, as part of that review, there ought to be a hearing on the operation of the 80/20 Rule. The 80/20 Rule permeates the whole US policy on imports of narcotic raw material and is paramount to any consideration of policy changes.

2.13 The Poppy Advisory and Control Board welcomed the requirement of the Anti-Drug Abuse Act of 1988 that there be a review of the U.S. Government's policy on the importation of narcotic raw material. The commissioning of the review was seen as a preliminary step in addressing the 80/20 Rule and its operation today.

C20437

1/19

9.

2.14 Whilst the Rule remains in place, there is no incentive for India to restructure its industry to make it more secure and relevant to customer needs and to bring production in line with demand and the requirements of the Single Convention. Whilst the Rule remains in place, little change apart from superficial and cosmetic adjustments can be expected to the Indian industry.

2.15 The preference given to the straw process and CPS as a narcotic raw material, evidenced in the Single Convention on Narcotic Drugs, has not been acknowledged by India. Indeed, the General Assembly of the United Nations, in Resolution No. 3279 (XXIX) of 10 December, 1974 spoke of the preference for the straw and CPS process over opium gum as it "lends itself to more effective control of illicit traffic when accompanied by efficient and effective enforcement procedures".

2.16 The Report to Congress entitled Licit Opium Review, prepared by the Department of State (Bureau of International Narcotics Matters) and the Department of Justice (Drug Enforcement Agency), December 1989, fails to adequately analyse and address problems and issues surrounding the operation of the 80/20 Rule.

3. REPORT TO CONGRESS - LICIT OPIUM REVIEW -
DECEMBER, 1989

3.1 The Report to Congress on Licit Opium Review by the Department of State and the Department of Justice, as required by the Anti-Drug Abuse Act 1988, came about as a result of the Administration finding unacceptable an earlier draft Report prepared by Mr. Rayburn Hesse of the Bureau of International Narcotics Matters, Department of State.

020437 /20

10.

3.2 The two Reports - the Hesse Report and the Report now before Congress - stand in marked contrast as to content, detail, findings and recommendations.

3.3 The Hesse Report presents a comprehensive analysis of international trade in licit and illicit narcotics and the implications for US Government policy on the import of narcotic raw material. The Hesse Report recommended the phasing out of the 80/20 Rule over a period of three years, to be complemented with aid and assistance, particularly to India, to address the urgent need for restructuring of the Indian industry and to address the increasingly serious problem of diversion from the licit Indian opium crop. It was found that the 80/20 Rule had not achieved its stated objectives.

3.4 By contrast, the Report to Congress by the State and Justice Departments recommends the retention of the Rule pending negotiations with India on a range of matters concerning the operation of the opium industry in that country.

3.5 There is much in the body of the Report to Congress which invites critical comment. However, in this testimony, comment is confined to the Findings and Recommendations made in the Executive Summary to the Report and, where necessary, reference is made to appropriate parts within the body of the Report itself.

3.6 In this testimony, the Findings and Recommendations are produced with an accompanying comment.

11.

3.7 Finding 1)

Current procedures, based upon the "80-20 Rule," have provided the United States with reliable sources for licit narcotic raw material (opium) for its pharmaceutical industry. Future needs can also be adequately met under this process.

Comment

3.8 By way of preliminary comment, there appears to be a lack of discipline throughout the Report in the use of the term "opium". At times it appears to be used to mean only opium gum, but in other texts it appears to be used as a word to cover all forms of narcotic raw material and not just exclusively opium gum.

3.9 If in the Finding quoted above the term "opium" is used in embracing all forms of narcotic raw material, then there is an apparent failure in the Report to appreciate that opium gum is a completely different narcotic raw material commodity from CPS. The failure to appreciate this distinction is also relevant if Finding 1) is only speaking of "opium" as opium gum.

3.10 Future needs of the industry cannot be met under the formulation of the 80/20 Rule as the Rule itself does not make the distinction between opium gum and CPS - or, for that matter, poppy straw - as narcotic raw materials.

3.11 With the decrease in the demand for opium gum in favour of CPS, and with the failure of Turkey in 1989 to produce sufficient quantities of CPS (a fact not noted in the Report to Congress), the 80/20 Rule will require US producers to purchase gum. Therefore, it cannot be asserted that the Rule, as administered and as drafted,

sadequately meets existing or future needs of the American industry. The Rule has turned out to be a static element in an industry which is dynamic and constantly changing as to customer needs and requirements.

3.12 In order to meet increasing demand for CPS, given the recent crop failure in Turkey, the Rule may be waived to allow greater imports into the US of CPS from the five other producers authorised under the Rule. If this were to be done, then the exception would become the rule and the 80/20 Rule would no longer apply.

3.13 Finding 2)

Unless the United States permits the growth of opium poppies within its borders, which the government has consistently opposed, the only source of licit opium is from foreign sources. The United States government supports the continuation of its program of reliance on such sources.

Comment

3.14 No comment.

3.15 Finding 3)

Because the licit American pharmaceutical industry can utilize both concentrate of poppy straw and opium gum in its manufacturing processes, to have only one supplier of opium gum is not detrimental to the industry. The major difference between CPS and opium gum is the lack of the alkaloid noscapine in CPS.

Since noscapine has no current medical use in the United States and has value solely to the extent that it can be exported (mainly to Japan), U.S. medical needs would not be affected by its absence. For this, and other reasons, the American industry generally prefers to utilize poppy straw. Thus, the reliance on opium gum production by India may hurt that producing nation's sales program in the future. Therefore, it would be to India's benefit to convert at least a part of its production to the poppy straw method so that it could remain competitive with other major licit producers.

Comment

3.16 Whilst the Report embraces the notion that one supplier of opium gum "is not detrimental to the industry", what is detrimental to the industry is the pre-eminent position given to that one supplier under the 80/20 Rule in respect of a commodity which is of declining relevance, not only in the US pharmaceutical industry but also world-wide.

3.17 The suggestion that part conversion of Indian production to CPS "so that it [India] could remain competitive with other major licit producers" may have the reverse effect. CPS production is a complex technical method requiring high capital investment in specialised equipment. Partial conversion may not prove economic in the Indian industry which already runs at a significant loss and requires massive subsidies from the New Delhi government. In addition, partial conversion to CPS will exacerbate the problem India faces in securing its industry. For ease of law enforcement, it is more practicable to prohibit all opium gum production.

3.18 Any opium gum discovered is therefore illegal and law enforcement simplified. Economics of scale and effectiveness of law enforcement methods dictate total conversion to CPS, not partial. |

3.19 Recommendations 4 A) and 4 B)

It is recommended that the "80-20 Rule" be maintained in its present form for an additional three years. This affirmation should not, however, translate to a full endorsement of the status quo.

A) During this period, the United States should continue to support India as a traditional supplier of the licit raw material, subject to the conditions of the Rule, while entering into negotiations with India to correct imbalances caused in part by the operation of the Rule.

These negotiations should encourage India to take action to reduce the opportunity for diversion from the field by expansion of enforcement and inspection control. The negotiations should also seek to assist India in reducing its opium stockpile and to bring its production into line with market conditions. India should also be encouraged to consider a partial conversion to the concentrate of poppy straw process.

B) The United States should continue to support Turkey as a traditional supplier of the licit raw material subject to the conditions of the "80-20 Rule".

However, the United States should actively encourage Turkey to consider production of alternative products as a means of utilizing the full capacity of its processing factory rather than to expand the areas of poppy cultivation.

Comment

3.20 The Report, whilst stating that the 80/20 Rule "be maintained in its present form for an additional three years" goes on to caution that this is not to be taken as a full endorsement.

3.21 It is necessary to address this comment with the observation made in the body of the Report, at page 20: "Nevertheless, the policy has been successful within the context of a more realistic set of expectations....."; and, at page 23: ".....The Rule is serving the purpose to which it is suited within its limits to influence conditions". Again, at page 23, it is stated: "The Review has shown that the 80-20 Rule has met its stated objectives and, with adjustments, can be expected to continue to do so while current conditions remain in effect.".

3.22 The support for the 80/20 Rule is therefore hedged about with qualifications. Indeed, the Report found it necessary to recast the objectives behind the Rule (see page 20) so that the Rule could be justified as having a modicum of success and credibility.

3.23 The fact remains that, irrespective of what the Report postulates as to the objectives behind the Rule (see page 20), the Federal Register* sets out the objectives as follows:

* See Federal Register, Volume 45, No. 30, Tuesday, February 12, 1980 - Proposed Rules, page 9289.

- 1) To avoid over-production and the accumulation of excess stocks of narcotic raw material; and
- 2) The prevention of diversion of licit product to the illicit market.

3.24 Irrespective of what the Report states, the facts show that the Rule has not met its objectives as set out in the Federal Register. When the performance of the Rule is measured against the objectives as recast by the Report, it cannot be stated to have met its objectives and the qualified endorsement of the Rule in the Report substantiates this fact.

3.25 The fact that the Rule has failed to meet its objectives is corroborated by the Report to the Committee on Foreign Affairs, U.S. House of Representatives, of May, 1989, on US Licit Opium Imports. At page 12, paragraph 2, the author (F. Marian Chambers) states: "The 80/20 Rule has not achieved its intended purpose, namely, preventing diversion to the illicit from licit production..... It has also probably encouraged inefficient production practices in Turkey and India."

3.26 The Recommendation in 4 A) displays a weakness with the analysis of the performance of the Rule contained in the body of the Report. First, the recommendation states that the US should continue to support India as a "traditional supplier". The notion of there being an internationally recognised group of producers known as "traditional suppliers" is not supported by the Single Convention on Narcotic Drugs. The notion of so-called "traditional suppliers" has crept into the lexicon of international narcotics through the Resolutions of the Commission on Narcotic Drugs. As

17.

020437

1/27

noted earlier in this testimony, the CND Resolutions on this subject are most likely ultra vires. Under the Convention, so-called "traditional suppliers" are accorded no particular status.

3.27 In strict terms, if the expression "traditional supplier" is to be used, then it only applies to producers of opium and not of CPS. In these circumstances, only India qualifies as a so-called "traditional supplier", not Turkey.

3.28 The expression "traditional supplier" is a misleading description purporting to confer some special pre-emptive but undefined status on certain producers of narcotic raw material.

3.29 The Recommendation seeks the continued support of the US for India and Turkey "subject to the conditions of the Rule". The Recommendation begs the question as to what are the "conditions of the Rule". In this respect, it is necessary to look at the record of the Recommendation by Administrative Law Judge Young to the Administrator, out of which the 80/20 Rule arose.* The Judge, at page 37, stated: "The US should not purchase narcotic raw materials or otherwise encourage production by countries that may not be capable of maintaining adequate control against diversion. Indeed, the proposed Rule would require the US to decline to import from any country which has not instituted and maintained adequate control systems for narcotic raw material as required under the Single Convention."

* Report to the Administrator, IN THE MATTER OF Proposed Limitations on Imports of Narcotic Raw Materials, DEA Docket No. 80-18, January 16, 1981.

3.30 Again, in the course of submissions to the Judge, it was pointed out that the US relying on India and Turkey for its source of supply of essential narcotic raw material will "result in the US losing considerable leverage over those countries to ensure they continue to maintain adequate controls against diversion. If there are no substantial alternative suppliers available to the US, because of the adoption of this Rule, the US may well find itself having to accept an inadequate level of control in order to obtain necessary supplies. The Rule thus exacerbates the situation it is intended to improve" (page 35). This statement, made in 1981, is now the actual situation under the 80/20 Rule.

3.31 The present inability of Turkey to supply the US market with CPS has placed India in a dominant position as a supplier. Indeed, before the shortage of CPS arose, the Rule - in practice - operated to protect the Indian industry, notwithstanding there was evidence of diversion to the illicit market. Furthermore, whatever leverage the 80/20 Rule was intended to have over India or Turkey, it apparently has not worked, particularly in the case of India, and has contributed to the diversion problem through protecting an archaic and increasingly insecure mode of production.

3.32 The Recommendation in the Report to Congress to seek negotiation with India to "correct imbalances" is a tacit acknowledgement of the failure of the Rule by a Report which seeks to continue the Rule in operation.

3.33 Whilst Indian opium under the Rule enjoys a guaranteed outlet in the US market, changes to the structure and operation of the Indian industry are likely to be only cosmetic and of transient effect. Guaranteed

market access given by the Rule derogates from any attempt to rationalise the industry or improve its security performance.

3.34 In respect of Recommendation 4 B), Turkey - as a supplier of CPS - does not warrant special consideration in the form of a guaranteed access to the US market. Turkey produces CPS and is a major producer of that commodity - except for the last year when severe frost decimated the Turkish crop. This event is not recorded in the Report to Congress and is of major importance to the operation of the 80/20 Rule.

3.35 Turkey, in producing CPS, produces a commodity that is increasingly sought by manufacturers of narcotic raw material. It is pertinent to note that the Report, in seeking to endorse continued support to both the Indian and Turkish industries, is recommending continued subsidisation of those loss-making industries by US pharmaceutical companies and their customers. Without the guaranteed access to the US market and the translation of that access into subsidisation, the Turkish and Indian governments would not be in a position to recover, in part, the cost of maintaining their industries.

3.36 The 80/20 Rule has not operated to control diversion, nor reduce stocks, in either India or Turkey. Indian stocks remain very high, as the INCB Report confirms. Turkish stocks are now exhausted, not due to any operation of the Rule, but due to three other factors:

- 1) Destruction of old and contaminated poppy straw through burning;
- 2) Dumping of CPS on the world market at depressed prices in order to promote sales; and

- 3) Effect of frost on the 1989 crop in cutting production from an estimated 41 tonnes of CPS to 8 tonnes (not dealt with in the Report to Congress).

3.37 Recommendation 5)

At the end of this three-year period, the "80-20 Rule" should be re-examined. Continuing or restructuring the Rule should be re-evaluated in part on the basis of the responses and actions of Turkey and India, the major licit opium producing nations, to the above.

Comment

3.38 At the end of a three-year period, following negotiations with Turkey, the Recommendation is that the Rule be re-examined. It is not stated how or by whom the re-examination is to be effected. It is not certain that the re-examination would invite submissions from interested parties or be conducted purely as an internal re-examination by the State Department and the DEA. There are no criteria against which the re-examination is to take place.

3.39 The suggested re-examination has all the appearances of a hastily conceived after-thought.

3.40 Recommendation 6)

The United States should provide direct and indirect assistance, to the extent available, to aid India and Turkey in meeting the stated objectives.

Comment

3.41 No explanation is given in the Report as to the meaning of "direct and indirect assistance". It is not clear what the words "to the extent available" mean. The Recommendation is heavily qualified and hedged about.

3.42 Importantly, it is not clear from the Report what the stated objectives are to which the assistance is given. The Recommendation appears to be meaningless. No assistance is found in the body of the Report to substantiate what is intended.

3.43 Recommendation 7)

In recognition of the favored position granted to the small group of licit opium suppliers, the United States should continue to be sensitive to any formal or informal agreements which seek to establish price levels above customary competitive levels. Such events would require immediate revision of the existing Rule.

Comment

3.44 The Recommendation recognizes that US customers may be held to ransom on prices for narcotic raw material due to the privileged position held by either India or Turkey under the 80/20 Rule.

3.45 The situation will be exacerbated as Turkey's present ability to supply CPS to the US market is almost non-existent due to crop failure. Under the 80/20 Rule, India will now command the position as principal supplier. There will be little or no competition for Indian opium as a raw material in the US domestic market.

3.46 This Recommendation is an acknowledgement of one of the principal faults of the Rule - the potential for either India or Turkey to dominate the market with the elimination of competition. This, alone, should prompt - as contemplated by the Recommendation - an immediate revision of the existing Rule.

3.47 The risk of unreasonable prices was addressed by Judge Young in the Report to the Administrator. At page 35, the Judge stated: "Reliance on a small group of countries also raises a significant risk that the American consumer will be paying an inflated price for narcotic medicines in the future. It would appear to be most unrealistic to expect price stability in a situation in which there are only two major suppliers and because of wide-spread medical insurance and the essential nature of the commodity and steadily increasing demand.".

3.48 The observation made in 1981 is relevant to the situation now emerging in 1990 with the likely dominance of India in the US market as the principal supplier of narcotic raw material due to the operation of the 80/20 Rule.

3.49 The maximum 20% share of the market given to producers other than India and Turkey does not operate to prevent domination and the consequential risk of unreasonable prices by either India or Turkey where either one is unable, for whatever reason, to supply the market with the required raw material.

4. SUMMARY

4.1 Recommendations 4 A) and 4 B) recognise the 80/20 Rule has failed.

4.2 Recommendation 4 A) specifically acknowledges that the Rule has:

- . created imbalances
- . not resolved the problem of stocks
- . failed to control diversion
- . failed to encourage the Indian industry to rationalise and up-date

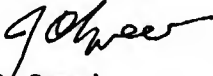
4.3 Recommendation 4 B) specifically acknowledges that Turkey has failed to abide by the provisions of the Single Convention on Narcotic Drugs as regards supply and demand, and that it gears its production of narcotic raw material to the capacity of its manufacturing plant to process straw into CPS contrary to the provisions of the Single Convention.

4.4 The Report and its Recommendations fail to address the specific terms of reference directed by Congress in the Anti-Drug Abuse Act 1988.

5. PROPOSED COURSE OF ACTION

5.1 Due to the many and varied complexities surrounding this issue, and the divergent views held and the various interests involved, it is recommended that the whole matter be the subject of a formal Hearing.

Thank you for the opportunity to present the Submission.



(J.O. Green)
Chairman
POPPY ADVISORY AND CONTROL BOARD

Appendices (2).

020437

/35

APPENDIX I.1. BACKGROUND TO THE DEVELOPMENT OF THE INDUSTRY IN
AUSTRALIA (TASMANIA)

1.1 In 1931, the Hungarian chemist, Janos Kabay, invented a process for extracting opiate alkaloids from the dry capsules of the biologically mature poppy (Papaver somniferum) plant. Because this process bypasses the opium stage - previously the only way of obtaining opiates from the poppy plant - it is considered to be the safer method for commercial production of opiates. The poppy straw process, as it is known, is the basis of the Australian opiates industry.

1.2 Some development work based on this process was undertaken in Australia by the Commonwealth Scientific and Industrial Research Organisation during the Second World War with trial work being carried out in a number of Australian States, including Tasmania. This work ceased at the end of World War Two and there was no further development until the 1960s when a United Kingdom based company, Macfarlan Smith, which had been undertaking trial work with poppies in England, extended its research base to Tasmania to find an alternative source for its codeine which, up to that time, was derived only from Indian opium.

1.3 Pilot production began on the North-West Coast of Tasmania in 1964/65, at which time Macfarlan Smith had become part of the U.K. Glaxo Group. The first season of production for alkaloids and poppy seed took place in 1970/71 when approximately 560 hectares of poppies were sown.

1.4 The cultivars used were based on the Northern European strain of poppy grown principally for oil seed production. The success of the early plant breeding work resulted in improvements in alkaloid yields of such magnitude that this variety of poppy was able to be adopted for commercial alkaloid production.

1.5 Technical breakthroughs in a number of areas provided the impetus for the development of the Australian poppy industry as a reliable and secure supplier of opiates to world markets:

- . new poppy varieties were developed with morphine yields well in excess of those previously contained in any other poppy growing countries;
- . poppy straw yields increased dramatically as a result of work done jointly by the poppy processing companies and the State Department of Agriculture on use of selective weedicides, fertilisers and irrigation and planting techniques; and
- . more efficient harvesting techniques were evolved by extensively modifying existing harvesting machinery.

1.6 Glaxo established the first poppy processing facility at Latrobe in Tasmania, which separated seed and poppy straw, and cleaned, graded and bagged poppy seed for export. For commercial reasons, Glaxo decided to modify an existing factory facility at Port Fairy in Victoria for use in the extraction of opiate alkaloids

from the poppy straw, rather than build a new extraction facility in Tasmania. Since the 1970/71 season, pelletised poppy straw has been shipped from Latrobe in Tasmania to Port Fairy in Victoria for processing.

1.7 In 1972, consideration was given by the Commonwealth and State Governments to an approach by a New South Wales based company, Abbott Australasia, to grow poppies in the State of New South Wales. The request was denied by joint decision of the Commonwealth and all State Governments and growing was restricted to Tasmania for reasons of security. This decision was conditional on the Tasmanian State Government establishing the Poppy Advisory and Control Board to:

- . advise on all matters relating to cultivation, production and transport of opium poppies and poppy material;
- . collect and collate statistical information and prepare reports; and
- . liaise with appropriate Australian Government Departments in the matter of Australia's obligations under the International Drug Conventions.

1.8 Abbott then began experimental work in Tasmania. In 1974/75, plans were set in train for an extraction plant to be built in Tasmania. This facility was subsequently built at Westbury, near Launceston in Tasmania. In 1982, ownership of the operation (Tasmanian Alkaloids) was transferred from Abbott to Johnson & Johnson, and Abbott's codeine conversion facility was moved from Kurnall in New South Wales to Westbury in Tasmania.

1.9 At present, some 600 growers are involved in growing around 5,000 hectares of poppies per annum for the two manufacturing companies (Glaxo and Tasmanian Alkaloids). From 5,000 hectares, the two companies harvest approximately 10,000 tonnes of poppy material, of which half is seed and half is poppy straw. The 5,000 tonnes of poppy straw yields about 50 tonnes of morphine equivalent, 90 per cent of which is exported. Almost all poppy seed produced is also exported to overseas markets for culinary use.

1.10 Reflecting high levels of expenditure on research and development and highly sophisticated agricultural and chemical processing techniques, Australian opiate alkaloid yields are now the highest in the world. The average commercial yield of morphine from poppy straw grown in Tasmania over the last five years was 1.00 per cent, compared with yields from Spain and France of 0.85 per cent and 0.60 per cent respectively. As well as growing poppies which are richer in morphine, Australia produces a greater volume of poppy straw from each hectare of poppies sown. The higher morphine content of the straw, combined with higher straw yields per hectare, means that a paddock of Australian poppies yields three to four times the quantity of morphine produced from a field of Turkish or Indian poppies. This has obvious security advantages.

1.11 Most poppy farmers grow other crops and a significant number also run livestock. The different nutritional requirements of the various vegetable and cereal crops, their different growing seasons, and the requirement not to grow poppies in the same paddock in consecutive seasons, makes poppies a good crop to grow in rotation with other crops and mix with livestock. The returns from poppy growing, relative to the effort required to grow them, compare favourably with most cereal and vegetable crops.

2. NATURE OF GOVERNMENT INVOLVEMENT

2.1 Responsibility for control of the poppy industry is mandated by the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol), and is shared by the Australian Federal Government and the Governments of the States of Tasmania and Victoria. Arrangements differ for opiate manufacture, export, and poppy cultivation; each is described in turn below.

2.2 In respect to opiate manufacture, the Australian Government (Commonwealth) Department of Community Services and Health is the "special administration" established in Australia under the 1961 Single Convention and has responsibility for approving manufacturing quotas for the production of opiate alkaloids from poppies grown in Tasmania. In exercising this function, the Commonwealth Department of Community Services and Health consults other agencies of the Australian Government and the Poppy Advisory and Control Board, which is an agency of the Tasmanian State Government.

2.3 Responsibility for authorising export of opiate alkaloids, as established under the Single Convention, is vested in the Commonwealth Director-General of Community Services and Health and is exercised through the authority of the Commonwealth Customs Prohibited Import and Export Regulations.

2.4 Cultivation of the poppy crop is controlled through the issue of a licence to grow to each farmer. The licensing system is the responsibility of the Tasmanian Government and is undertaken by the Poppy Advisory and Control Board. The total area to be licensed is based on the manufacturing quota established by the Commonwealth Department of Community Services and Health.

The manufacturing quota is based on estimates of likely sales by the two poppy processing companies and a determination of the appropriate level of reserve stocks of raw material to be held by the two companies. Manufacturing quotas and licensed areas are varied to ensure that the level of opiate stocks does not exceed that required for normal trading purposes.

2.5 Close consultation between the Commonwealth Department of Community Services and Health, the Poppy Advisory and Control Board and the two poppy processing companies is essential because of the need to license sowing areas in the year prior to the setting of manufacturing quotas.

2.6 The Poppy Advisory and Control Board also has responsibility for advising the State Government on any matters affecting the long term viability of the Tasmanian industry.

3. SECURITY

3.1 Growing poppies for poppy straw and producing opiates using the poppy straw process is of itself an advantage in ensuring there is no leakage of opiate raw material into the illicit market. As indicated in Operative Paragraph 2 of the 1974 U.N. General Assembly Resolution on Opiates, a security and control strategy based on unincised poppy cultivation and use of the poppy straw process, and accompanied by "efficient and effective enforcement procedures", lends itself to "more effective control of illicit traffic". Government authorities in Australia have devised a security and control programme which effectively controls the leakage of licitly grown opiates into the illicit market.

3.2 Government responsibility for the security/law enforcement aspects of the poppy industry is jointly shared by the State Police of Tasmania and Victoria, the Australian Federal Police, the Commonwealth Department of Community Services and Health (DCSH), the Australian Customs Service (ACS) and the Tasmanian Poppy Advisory and Control Board (PACB). Current arrangements provide for:

- . field security to be primarily the responsibility of State authorities, ie. the Poppy Advisory and Control Board (PACB) and Tasmania Police;
- . factory operations and movements within the States of Tasmania and Victoria to be a joint responsibility of the PACB, Tasmania Police, Victoria Police, Australian Federal Police (AFP) and the Commonwealth Department of Community Services and Health (DCSH); and

- . exports outside Australia to be the responsibility of AFP, DCSH and the Australian Customs Service (ACS).

3.3 At all stages, there is close consultation with the two poppy processing companies and, on matters relating to field security, the poppy growers are also actively involved. Indeed, both the companies and the growers make substantial commitments towards industry security - the companies themselves expend substantial resources on general site security and security related to movements, and the farmers (who are the first line of defence against interference) liaise closely with the PACB, poppy processing company field officers and Tasmania Police on field security.

3.4 A working group of Australian and State Government officials, known as the Committee on Poppy Industry Security (COPIS), has been established to discuss security issues. Its main objective is to ensure that there are no weak links in the security cover from poppy field through to the export of the finished product overseas or its use within Australia. Its establishment was prompted by a concern on the part of all Government agencies involved in security that criminal elements may attempt to exploit any gaps or weak links in the security chain.

3.5 Under Tasmanian law, no person may grow or cultivate the poppy or have in his possession any part of the poppy plant (Papaver somniferum and Papaver bracteatum) except the seeds, unless duly authorised, and the penalties for infringement are severe. A Tasmanian Government licence to grow poppies is issued to a farmer only after he has contracted to grow and dispose of the crop (when harvested) to a licensed manufacturer.

The granting of a State Government licence is also subject to the grower receiving a clean "bill of health" from the Police. The licence application must be accompanied by an exact map grid reference of the grower's residence and the fenced paddock where it is proposed that poppies be cultivated.

3.6 Field inspections are made of all licensed growers by the Board's field officers based in Devonport and Launceston in the north of Tasmania, and Hobart in the south. Field officers carry out regular and frequent inspections of growing poppy crops, and also inspect currently and previously licensed farms to prevent regrowth of poppies after harvesting. Liaison is also maintained between the Board's field officers, poppy processing company field staff and Department of Agriculture field extension officers, by regular inspection of crops in the company of these officers.

3.7 The Australian approach to crop security has been to co-ordinate the resources available in industry, Government and the rural community to achieve an effective security and control programme, at minimum cost to all concerned. Resources are utilised from a number of different sectors outside of the Poppy Board itself:

- . growers are the foundation of the field security effort. Particular emphasis is placed on poppy growers themselves checking and reporting any suspicious activity in the vicinity of their crop. Farmers and others living in close proximity to poppy crops are supplied with self-carboning pads on which they make a note of any unusual or suspicious activity around poppy crops, including the description and registration of unusual motor vehicles. These reports are then sent to

the local police for forwarding to Police Drug Intalligenca where they ere analysed. This system has been vary successful end has resulted in arrests for a range of offences, not all of which hava involved poppies.

- . company field officers employed by the two poppy processing companies are responsible for various agronomic aspects of the cultivation of the crop - arranging contracts, sowing, spraying, harvesting, etc. They have also devaloped a keen security sense and liaisc very closely with the PACB and Police in reporting any incidents or suspicious activity. Meetings are held with company field staff from time to time to keep them informed of trends in crop interference and security.
- . Tasmania Police provide substantial resources in the areas of detection, apprehension, prosecution, information gathering, intelligence processing and dissemination and task force operations. Over the past three seasons, a joint task force operation has been established. This involves a 16 man team within tha Tasmania Police Drug Bureau, which works closely with the Poppy Advisory and Control Board.

The Board's own field officers provide tha link between growers, company field officers and Polica officers, and the Board acts as overall co-ordinating authority.

3.8 While the low morphine content of poppy straw - only 1% compared to 10% for Indian opium - and the difficulty of extraction makes poppy straw less vulnerable to illicit trafficking, Australian authorities do not underestimate the risk of diversion of poppy straw. Harvesting and crop transportation operations are closely controlled, and the harvest operators play a part in the detection of thefts of capsules from poppy fields. The Board's field officers are directly involved in a supervisory role in harvesting, regularly checking harvesters and harvest operations to ensure proper security procedures are being followed. The dry poppy material collected by the harvesters, which is a mixture of capsule, stem and seed, is mechanically transferred from the harvesters' hoppers on to trucks fitted with seed-tight bins for transport to the factory. The bulk bins are inspected to ensure that there are no defects which could cause seed spillage. As a consequence, there is very little regrowth from seed spillage en route to the factory. Any regrowth which does occur is quickly destroyed. Random checks are also carried out on trucks transporting poppy material from the field to the processing factories. On arrival at the factory the trucks enter a security area for tare weighing of the capsule/seed mixture and samples are taken by the company concerned in order to assess the value of the consignment for the purpose of payment to the grower. The load is then mechanically transferred to secure storage.

3.9 Security during manufacture is the responsibility of each of the two extracting companies under Government supervision. Strict measures are enforced.

Glaxo Australia: All crops grown under contract for Glaxo are delivered to the seed separation and crop storage plant at Latrobe in Tasmania, which is licensed

by the Tasmanian Department of Health Services. There is no further control over the seeds, which are cleaned and packed for sale for culinary purposes or oil extraction. The poppy straw is compacted, packed and shipped across Bass Strait to the extraction plant at Port Fairy in Victoria. The movement of compressed straw is under strict security via container ship and secure road transport with inspection at departure, transit and arrival points. The company is subject to regular inspection and is required to keep records of total weight of crop received and straw obtained. The Commonwealth Department of Community Services and Health (DCSH) licenses the extraction plant under the Commonwealth Narcotic Drugs Act, approves in conjunction with the Federal and State Police Departments the security arrangements for transport of poppy straw from Tasmania to Victoria, and makes regular inspections.

Tasmanian Alkaloid (Johnson & Johnson) is licensed by both the Australian and Tasmanian Governments to manufacture poppy straw concentrate, other opiate alkaloids and derivatives at its extraction plant at Westbury in Tasmania, subject to the requirement that they maintain detailed records on crop receipts, straw processed, and alkaloid manufacture and storage, and have approval for their security and storage arrangements. Federal and State Government inspectors, operating as a team, regularly inspect records and stock and check security requirements. Factory security is strictly maintained at a high standard.

3.10 The movement within Australia of concentrate of poppy straw is subject to stringent security measures including armed escorts for ground movement, special arrangements for air transport, and supervision by Australian Federal Police and secure storage at airports upon trans-shipment. All movements are covered by detailed and comprehensive documentation.

020437 / 47

APPENDIX 2.

HISTORY OF POPPY GROWING IN TASMANIA

YEAR	HECTARES HARVESTED	TONNES HARVESTED (seed and straw)
1965-70	665	N/A
1971	598	N/A
1972	866	N/A
1973	1,308	N/A
1974	797	N/A
1975	834	1,432
1976	2,799	3,681
1977	5,783	9,071
1978	6,854	9,280
1979	8,774	15,329
1980	1,531	2,334
1981	3,742	5,703
1982	2,459	4,095
1983	5,273	8,533
1984	5,738	9,306
1985	4,899	10,738
1986	3,993	9,119
1987	3,280	6,647
1988	3,462	6,467
1989	4,581	8,155
1990	4,500*	N/A

* provisional estimate

APPENDIX 7.—TESTIMONY OF GLAXO AUSTRALIA PTY., LTD.**Introduction**

Glaxo Australia has been a reliable and secure supplier of narcotic raw material to the United States since 1981, and currently supplies approximately 7.6 tonnes AMA of concentrate of poppy straw to the United States, which amounts to 12.5% of the United States market. This equates to 62.5% of the maximum 20% permitted under the 80/20 Rule. Glaxo Australia urges elimination of the 80/20 Rule phased over a period of three years, after which United States market preferences for India and Turkey would cease.

Background

Glaxo Australia Pty. Ltd. is an autonomous member of the Glaxo Group, which is based in London and headed by the parent company Glaxo Holdings p.l.c. The Glaxo Group is the third largest pharmaceutical company in the world in terms of sales, with some 35,000 employees in subsidiary and associated companies in 70 countries. Glaxo Group's products are sold in 150 countries. Total sales in 1988 were £2,059 million.

Glaxo Australia is Australia's leading pharmaceutical company. Its headquarters are in Melbourne, with factories in Melbourne, Port Fairy (Victoria), and Latrobe (Tasmania).

Glaxo Australia's Chemicals Division produces, among other products, narcotic raw materials that are processed and manufactured into morphine, codeine, and other pain relieving drugs. These products are processed for domestic consumption as well as export.

The Australian opiate alkaloid industry is based in the island state of Tasmania. There, farmers grow the morphine poppy *papavar somniferon* under contract to Glaxo Australia or another processing company, Tasmania Alkaloids Pty. Ltd.

Australian processors use the concentrate of poppy straw method of production. By this method, the poppies are left to dry in the fields, then their alkaloid-rich capsules are harvested mechanically. The "straw" is then moved to a processing facility in Latrobe, where seeds are separated from the straw. Seeds are sold in international culinary markets.

The straw is processed, pelletized, and shipped to Glaxo Australia's modern processing facility in Port Fairy. Here, by sophisticated chemical processes, the pelletized straw is refined into concentrate of poppy straw (CPS).

The main ingredient of CPS is anhydrous morphine alkaloid (AMA), which constitutes approximately 80% of the substance. This is the maximum purity permitted to be imported into the United States. The balance consists mainly of water and other organic vegetable matter.

Glaxo Australia's production and sale of CPS are heavily regulated. The Tasmanian Poppy Advisory and Control Board (PACB) licenses Tasmanian farmers to grow poppies based on contracts they have signed with Glaxo Australia or Tasmania Alkaloids. The amount of cultivation permitted is based on estimates of demand ascertained by the processors from their customers, and approved by the PACB and the relevant Australian Government authorities. The approvals are then forwarded to the United Nations International Narcotics Control Board (INCB) based in Vienna. This procedure is required by the 1961 Single Convention on Narcotic Drugs, which governs world-wide licit narcotic production and manufacture.

Poppies are grown only on licensed identified plots. Strict security is provided by the PACB. There is no diversion to illicit markets.

The annual world market for licit narcotic raw material is approximately 200 metric tonnes. The primary producers are India, Turkey, Australia, and France. India produces gum opium; Turkey, CPS; and Australia and France, CPS with or without thebaine. According to the most recent figures published by the INCB, production totals for these countries in 1988 are as follows:

	Tonnes AMA	
India	61.89	(Opium)
Australia	39.20	(CPS)
Turkey	33.47	(CPS)
France	27.88	(CPS)
TOTAL	162.44	

The major consumer nations of narcotic raw materials are the United States, USSR, and the United Kingdom. Consumption of each country, based on INCB statistics, is as follows:

	Tonnes AMA		Total*
	Opium	CPS	
USA	21.0	42.8	63.8
UK	4.4	22.35	26.75
USSR	13.75	0	13.75
OTHER	0	0	95.7
TOTAL			200.0

*Total includes stock

In 1989, Glaxo Australia processed 30 tonnes AMA of CPS. Of this amount, 7.6 tonnes were sold to United States customers (Penick & Mallinckrodt), and 22.4 tonnes were sold customers in other countries.

80/20 Rule

Glaxo Australia's shipments of narcotic raw material to the United States are limited by a policy of the Drug Enforcement Administration known as the 80/20 Rule (21 CFR 1312.13). According to this policy, narcotic raw material, which is defined as opium, poppy straw, and concentrate of poppy straw, imported into the United States can have as its source one of seven countries, namely Turkey, India, Yugoslavia, France, Poland, Hungary, and Australia. At least eighty percent must be from Turkey and India, with the balance from among the remaining five countries. The only exception to the Rule would occur "under conditions of insufficient supply."

The 80/20 Rule was adopted by the United States Drug Enforcement Administration in 1981 following publication of an Advanced Notice of Proposed Rulemaking (44 Federal Register 114, 33695, June 12, 1979); Notice of Proposed Rulemaking (45 Federal Register 30, 9289, February 12, 1980) and written public comment and oral testimony. The Final Rule (46 Federal Register 159, 41775, August 18, 1981) took effect September 17, 1981.

Glaxo Australia contends that the 80/20 Rule has failed to achieve its objective of reducing excessive stocks of narcotic raw material and preventing diversion to illicit markets, and has contributed little to control efforts. The United States market for narcotic raw material is roughly 60 tonnes AMA, which is only one-third of the world market. The remaining two-thirds of the world market, roughly 140 tonnes AMA, is free and open, restricted only by the dictates of the Single Convention. This non-United States market is large enough to attract new entrants, without taking into account the United States share. Yet there has been no proliferation of new sources, as feared by the INCB in 1979. Granted, world production and consumption have been in relative balance, but India's excessive stockpiles persist and appear to be increasing.

The existence of the 80/20 Rule certainly has not contributed to lessening Indian diversion because by all accounts it is on the rise. The Bureau of Narcotic Matters of the United States Department of State reported in August of 1989 that opium diversion from the licensed Indian crop ranges from 10% to as high as 50% of the registered crop level. Since official production was 600 tonnes of opium, between 60 and 300 tonnes of opium were diverted to the black market.

Glaxo Australia questions whether the United States government should continue to give India preferred status as a

supplier of licit narcotic raw material when India's ability to maintain adequate controls over its licensed crop is so poor.

The 80/20 Rule has also not contributed to reducing excessive stockpiles in Turkey and India. Turkey's stockpiles have been depleted by the combined effect of the 1988/1989 drought and increasing world demand for CPS. India's stockpiles continue to grow. Their current stocks reportedly exceed 2,000 tonnes of opium, which is enough to supply the world's licit narcotic raw material needs for more than one year, or the world's licit opium needs for three years.

The "Licit Opium Report" submitted to Congress recommends the 80/20 Rule "be maintained in its present form for an additional three years." Glaxo Australia believes that the 80/20 Rule has failed to achieve its stated objectives and urges a formal administrative review process be initiated so that all affected parties can present their submissions and evidence on this complex issue. Glaxo Australia's preferred objective is the elimination of the Rule, phased over a period of three years, after which time United States market preferences for India and Turkey would cease.

The rationale for this progressive phasing out of the 80/20 Rule is to enable all affected parties, particularly producers and manufacturers, to adjust to the changed circumstances. To prevent proliferation of narcotic raw material producers, the current seven authorized producers would be maintained.

If strictly observed, the provisions of the Single Convention are adequate to regulate world licit narcotic production and distribution. The overlapping 80/20 Rule, applying as it does to only 33% of the world market, has little benefit. On the other hand, by providing United States market protection to India, the 80/20 Rule encourages India to cling to an antiquated system that damages world illicit narcotic control efforts.

APPENDIX 8.—TESTIMONY SUBMITTED BY NUZHET KANDEMIR,
AMBASSADOR, TURKISH EMBASSY, WASHINGTON, DC

TURKISH EMBASSY
WASHINGTON, D.C.

March 21, 1990

House Judiciary Committee,
Crimes Subcommittee
House of Representatives
207 CHOB
Washington, D.C. 20515

Dear Mr. Chairman,

I have the pleasure to submit testimony explaining Turkish perspectives on the current quota system for the importation of pharmaceutical raw materials to the United States for the consideration of the Crime Subcommittee.

As you know, current federal law mandates that the needs of the American narcotics raw materials market be filled by Turkey, India, France, Poland, Hungary, Yugoslavia, and Australia. Furthermore, eighty percent of this import market is reserved for the traditional poppy producers, Turkey and India. Turkey is intimately concerned with any possible decisions pertaining to the 80 per cent quota reserved for traditional producers.

In collaboration with the US Administration and to support US policies, Turkey banned the cultivation of lanced poppy capsules against the primary interest of 1.5 million farmers and dedicated scarce resources to the implementation of an expensive system which prevents the leakage of raw opium into the illicit market.

While Turkey is expected to recover financially from the implementation of this costly system, you can understand my government's concern over any prospective change to the 80 per cent quota. The overview I will present and the close cooperation between our two countries in drug abuse control efforts, argue against any changes by the US which would undermine our long-standing and highly successful cooperation.

As a comparatively small market with a need for strict controls, it is very important that narcotics production not be perceived and treated as any other commercial issue whose resolution can be sought through free market competition.

The opium poppy has been grown in Anatolia for 5,000 years. Turkish farmers grow poppies in poor soil where cultivation of substitute crops is practically impossible. In many of these areas, it is the only source of income for farmers. Oil is extracted from its seeds and used for cooking and the paint industry. The seeds are also used in making cakes and pastries, and the residue of the seeds is used as animal feed. Thus, in certain regions of Turkey, poppy cultivation has considerable economic significance.

Turkish poppy farmers were free of any restrictions until 1933, when Turkey became party to the International Opium Convention. The Turkish Grain and Opiate Board (TMO) was established in 1938, and since that date has controlled the production, purchase, standardization, and export of opiates, as well as the distribution of drugs for medical requirements.

From 1938 to 1971, TMO purchased and exported opium gum with the highest morphine concentration in the world. This was extracted by the traditional method of lancing the poppy capsules and collecting the seeping gum from the poppy. Due to the high morphine content, Turkey held roughly 50 percent of the licit international opium market.

In the 1960's, the unfair campaign accusing Turkey of being one of the sources of illicit drug trafficking intensified and consequently, the Turkish Government imposed a total ban on poppy cultivation in 1971. The ban adversely affected the population, which depended on legal poppy farming for its only income. Moreover, the ban did not prove useful in the international control of narcotics since Turkey was not the source of the problem.

When production resumed, it was under entirely different conditions. Turkey banned the lancing of poppy capsules and adopted the "poppy straw method" (CPS), under which dried unlanced capsules are converted through an expensive chemical process to morphine base, thereby guaranteeing the inavailability of opium gum for illicit traffic. Poppy fields are licensed through TMO and carefully inspected to ensure that there has been no lancing of the poppy capsules.

Turkey's willingness to commence CPS production was merely one manifestation of her dedication to eliminating illegal drug use and illicit trafficking world-wide. However, in the years between Turkey's voluntary cessation of lanced poppy cultivation and the commencement of CPS production, others stepped in to fill the vacuum left in the international opium derivative market when encouraged to do so by pharmaceutical companies.

Turkey has paid a very high price for this conversion, which was undertaken to ensure that there would be no illicit diversion of Turkish opium gum to the international market. In addition, the enforcement program is very expensive. The licensing process, plus continual surveillance of the crops on land as well as by helicopter and light aircraft costs the Turkish government enormously. Finally, the cost of producing morphine base through the CPS chemical process is much higher than through the traditional opium gum process. Hence it is difficult to compete for international sales with countries deriving their morphine base from opium gum.

Turkey agreed to convert to the CPS method of production after extensive consultations with the United States Government. Realizing the sacrifice involved with the conversion, the United States committed to guaranteeing Turkey a substantial share of its market for morphine-derived pharmaceuticals. To fulfill this commitment, the

United States established a regulation under which Turkey and India are jointly guaranteed 80% of the market. However, there is no subdivision of the 80%, that is, the two countries compete for their share.

Between 1981 and 1986, Turkey's CPS export to the US remained very low since the Turkish product was inevitably costly. However, in 1987, the U.S. market began to shift in Turkey's favor. A major U.S. drug company patented a process to derive a valuable trace element out of CPS-derived morphine, possible before only out of morphine, derived from opium gum. In addition, stocks of another element derived from opium gum reached very high levels, posing a security problem. This led manufacturers to seek the Turkish product, and sales rose to 31 tons in 1987 from only 2.2 tons in 1986.

As one of the world's largest poppy-producing nations, and one of the primary fighters against the illicit use and trafficking of drugs, Turkey has always believed in the necessity for international cooperation. Therefore, she became a signatory to the 1961 Single Convention on Narcotic Drugs, as well as to the 1971 Convention on Psychotropic Substances. Turkey has also played a leading role in the international control effort of precursors and other special chemicals which are used in the processing of drugs. In many statements of the United Nations Economic and Social Council (ECOSOC), Turkey has been upheld as a traditional producer of the opiates. Turkey was a member of the UN Commission on Narcotic Drugs from its establishment until this year, and, for many years, has held the chairmanship of the UN Subcommittee on Illicit Drug Trafficking and Related Matters in the Near and Middle East. She played a key role in its recent expansion to include India and almost all of the Arab countries in the region.

In 1974, with the assistance of UNFDAC, which invested approximately US\$4 million in a control system and aerial surveillance designed to identify illegal crops, Turkey began a program involving licensing and government purchasing at guaranteed prices in seven provinces in central Anatolia. All other poppy cultivation in those provinces and elsewhere was completely and effectively banned. UNFDAC and Turkey have maintained their positive relationship, and Turkey's success in its implementation of the CPS method has been widely acclaimed by the International Narcotics Control Board (INCB), the world's most effective narcotics control organization, and the US Drug Enforcement Administration as well. Currently, Turkish farmers are allowed to cultivate poppies only in regions under the strict supervision of authorities. One should note that, geographically, Turkey is located between the illegal producers of the East and the consumers of the West, making her a linchpin in the war against drug trafficking. Her contributions to this global battle have made her a model for other nations.

Following are some facts and figures concerning CPS production in Turkey. At this time, TMO has 12.5 tons of AMA stock, which corresponds to 25 tons of CPS. Parenthetically, all 25 tons can be exported to the US. CPS is currently not under production; however, as soon as the poppy is harvested, production will resume and exportation will begin in September.

TMO states that it is available at any time to enter into negotiations with US pharmaceutical companies. It already has a long term contract with the Penick Co., dating back to July 15, 1987; and has been concluding agreements via telex with Mallinkrodt, Johnson & Johnson and First State Chemical. TMO gladly partakes in such productive, working relationships.

With respect to pricing policy, TMO sets prices according to world market dictates, and has at times set them lower. In fact, as is well known, TMO has even been accused in the past by other exporting countries of dumping its product. I hope this will dispel any false notion that TMO is raising its prices artificially.

Concerning the question of Turkey's ability to satisfy the US market demand for CPS, one should note that TMO's Bolvadin plant has the capacity to process 20,000 tons of poppy-straw and produces 90 tons of CPS. Ordinarily, 80 tons of CPS can be exported. Therefore, Turkey could obviously satisfy the entire US market demand of 85 tons.

Furthermore, the General Directorate of TMO has informed this embassy that it will reserve 40 tons of CPS (20 tons AMA) for the US market after the 1990 crop is processed.

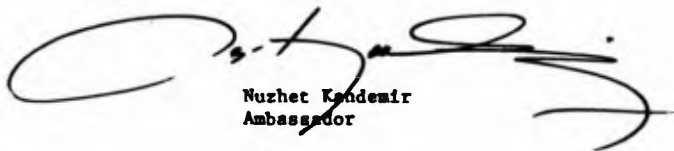
In conclusion, I would like to reiterate that Turkey has sought to contribute to international efforts to control drug trafficking and abuse, and has gone to considerable ends to cooperate with US and international drug control policies. Maintenance of the current US narcotics raw materials quota is in the best interests not only of my country and its economy but also our countries' mutual endeavors to curb opium diversion to the illicit market. It is our hope that the Crime Subcommittee will therefore recommend the continuation of current policy.

I believe that the testimony I have submitted fully explains Turkey's position, and I hope I have addressed any questions you may have had. If you would like more information, please feel free to contact me or Mr. Berk Dibeck, Counsellor, at 659-8200.

I would like to avail myself of this opportunity to assure you of my highest consideration.

Yans

Sincerely,



Nuzhet Kandemir
Ambassador





